Asia Partnership Conference of Pharmaceutical Associations (APAC)

Analysis Report

ver. 2016

Identification and Clarification of the Differences in Regulatory Requirements between Asian Economies

APAC Regulations and Approvals Expert Working Group

April 7, 2016
Tokyo, Japan

Member Associations	
HKAPI	Hong Kong Association of the Pharmaceutical Industry
IPMG	International Pharmaceutical Manufacturers Group
IRPMA	International Research-Based Pharmaceutical Manufacturers Association
JPMA	Japan Pharmaceutical Manufacturers Association
KPMA	Korea Pharmaceutical Manufacturers Association
KRPIA	Korean Research-based Pharmaceutical Industry Association
OPPI	Organization of Pharmaceutical Producers of India
PhAMA	Pharmaceutical Association of Malaysia
PHAP	Pharmaceutical and Healthcare Association of the Philippines
PreMA	Pharmaceutical Research & Manufacturers Association
RDPAC	China Association of Enterprise with Foreign Investment R&D-based Pharmaceutical Association Committee
SAPI	Singapore Association of Pharmaceutical Industries

Abbreviation

Abbreviation	Description
ACTD	ASEAN Common Technical Document
A.O.	Administrative Order (Philippines)
ADR	Adverse Drug Reaction
AE	Adverse Event
AIDS	Acquired Immune Deficiency Syndrome
API	Active Pharmaceutical Ingredient
ARs	Adverse Reactions
ASEAN	Association of South-East Asian Nations
BE	Bioequivalence
BLA	Biologics License Application
BP	British Pharmacopoeia
BPOM	Badan Pengawas Obat dan Makanan (Indonesian national agency of drug and food control)
BSE	Bridging study evaluation (Taiwan)
CDCR	Control of Drugs and Cosmetic Regulation (Malaysia)
CDE	Center for Drug Evaluation
CDFS	Council on Drug and Food Sanitation(Japan)
CDRR	Center for Drug Regulation and Research (Philippines)
CDSCO	Central Drugs Standard Control Organization (India)
CEP	Certification of Suitability to the monographs of the European Pharmacopoeia
CFDA	China Food and Drug Administration
CFDI	Center for Food and Drug Inspection
cGMP	current Good Manufacturing Practice
Ch.P.	Chinese Pharmacopoeia
CHGRAO	China Human Genetic Resources Administration Office
CIOMS-I	Suspect Adverse Reaction Report Form (CIOMS Form I)
CIRB	Centralised Institutional Review Board (Singapore)
c-IRB	Central IRB
CMC	Chemistry, Manufacturing and Control
CoA/COA/CA	Certificate Of Analysis
CPP	Certificate of Pharmaceutical Product
CRC	Clinical Research Centre
CRF	Case Report Form
CRMC	Clinical Research Management Committee
CRO	Contract Research Organization
CSR	Clinical Study Report
CT	Clinical Trial
CTA	Clinical Trial Application
CTA	Clinical Trial Authorization
CTA	Clinical Trial Approval
CTC	Clinical Trial Certificate
CTD	Common Technical Document
CTIL	Clinical Trial Import License （Malaysia）
CTM	Clinical Trial Material
CTN	Clinical Trial Notification
CTRI	Clinical Trials Registry- India
CTT	Clinical Trial Team
CTX	Clinical Trial Exemption
CV	Curriculum Vitae
DB	Double Blind
DCA	Drug Control Authority (Malaysia)
DCGI	Drugs Controller General India
DMF	Drug Master File
DOH	Department of Health
DP	Drug Product
DRGD	Drug Registration Guidance Document （Malaysia）
DS	Drug Substance
EC	Ethical/Ethics Committee
EMEA/EMA	European Medicines Agency
EP	European Pharmacopoeia

Abbreviation	Description
EPAR	European Public Assessment Report
EPW	Empowered Procurement Wing (India)
ERB/ERC	Ethical Review Board/ Committee (Philippines)
EU	European Union
FDA	Food and Drug Administration (U.S.)
FDC	Fixed Dose Combination
FERCIT	Forum for Ethical Review Committees in Thailand
FIH	First in Human
FIM	First in Man
FSC	Free Sale Certificate
FtoF or F2F or FTF	Face to Face
FY	Fiscal Year
GCP	Good Clinical Practice
GDA	Generic Drug Application
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GMP CERT	GMP Certification
GpvP	Good Pharmacovigilance Practice
GS-1	Global Standard One
GSB	Global Safety Board
GTIN	Global Trade Item Number
HA	Health Authorities
HAS	Health Sciences in Singapore
HGR	Human Genetic Resources
HIV	Human Immunodeficiency Virus
HKD	Hong Kong dollar
HKOP	Hong Kong Office of President
HSA	Health Sciences Authority (Singapore)
IB	Investigator's Brochure
IC	Informed Consent
ICF	Informed Consent Form
ICH	The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICH E5	ICH E (Efficacy) 5 Guideline (Ethnic Factors in the Acceptability of Foreign Clinical Data)
ICH E6	ICH E (Efficacy) 6 Guideline (Good Clinical Practice)
ICSR	Individual Case Safety Report (Philippines)
IDL	Import Drug Licence （China)
IDR	Indonesia Rupiah
IEC(EC)	Independent Ethics Committee
IMCT	International Multi-Center Clinical Trial
IMP	Investigational Medical Product
IND	Investigational New Drug
IP	Indian Pharmacopoeia
IRB	Institutional Review Board
JP	Japanese Pharmacopoeia
KOMNAS	The Indonesian Human Rights National Commission (Komnas HAM)
KP	Korean Pharmacopoeia
LOA	Letter of Authorization
LTOC	List of Table of Contents
MAH	Marketing Authorization Holder
MF	Master File (Japan)
MFDS	Ministry of Food & Drug Safety (Korea)
MHLW	Ministry of Health, Labour and Welfare (Japan)
MOPH	Ministry of Public Health (Thailand)
MRCT	Multi-Regional Clinical Trials
MREC	Medical Research & Ethics Committee (Malaysia)
MTA	Material TransferAagreement
NAFDC	National Agency for Drug and Food Control (Indonesia)
NBC	New Biological Entity
NCCR	National Committee for Clinical Research (Malaysia)

Abbreviation	Description
NCE	New Chemical Entity
NDA	New Drug Application
NDAC	New Drug Advisory Committee (India)
NF	The National Formulary
NHG-DSRB	National Healthcare Group Domain-Specific Review Board (Singapore)
NIBIO	National Institute of Biomedical Innovation (Japan)
NIFDC	National Institutes for Food and Drug Control (China)
NME	New Molecular Entity
NPCB	National Pharmaceutical Control Bureau (Malaysia)
NRBP	National Research Program for Biopharmaceuticals (Taiwan)
NSAE	Non Serious Adverse Event
OTC	Over-The-Counter
PAL	Pharmaceutical Affairs Law
PBRER	Periodic Benefit Risk Evaluation Report
PD	Pharmacodynamics
PFDA	Provincial Food and Drug Administration (China)
PHREB	Philippine Health Research Ethics Board
PI	Principal Investigator
PI	Package Insert
PIC/S	Pharmaceutical Inspection Convention (PIC) / Pharmaceutical Inspection Co-operation Scheme（PICS）
PIL	Patient Information Leaflets
PK	Pharmacokinetics
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PMS	Post-Marketing Surveillance/Study
PNHRS	Philippine National Health Research System
PP	Philippine Pharmacopoeia
PSD	Product Services Division (Philippines)
PSUR	Periodic Safety Update Report
r-DNA	recombinant DNA
REMS	Risk Evaluation and Mitigation Strategy
RFID	Radio Frequency Identifier
RM	ringgit
RMB	renminbi = CNY (CHINESE YUAN)
RMP	Risk Management Plan
RRC	Research Review Committee (Malaysia)
Rs	Rupee
S&E	Safety & Efficacy
SAE	Serious Adverse Event
SEC	Subject Expert Committee
SKU	Stock Keeping Unit
SMF	Site Master File
SMP	Safety Monitoring Program (Thailand)
SMPC/SmPC	summary product characteristics
SOP	Standard operating procedure
SQOS	Singapore Quality Overall Summary
STM	Specification & Test Method
SUSAR	Suspected Unexpected Serious Adverse Reaction
TB	Tuberculosis
TFDA	Taiwan Food and Drug Administration
Thai-FDA	Thailand Food and Drug Administration
TOX	Toxicology
UP-PGH	University of the Philippines - Philippine General Hospital
US	United States
USP	United States Pharmacopoeia
WHO	World Health Organization

Survey Results
Data sheets from Each Economy
on the areas of IND, NDA, Clinical Trials and GMP Evaluation System

China	(RDPAC)
Hong Kong	(HKAPI)
India	(OPPI)
Indonesia	(IPMG)
Japan	(JPMA)
Korea	(KPMA)
Korea	(KRPIA)
Malaysia	(PhAMA)
Philippines	(PHAP)
Singapore	(SAPI)
Taiwan	(IRPMA)
Thailand	(PreMA)

Item	Contents	Detail or Example	China RDPAC	Hong Kong HKAPI	India OPPI	Indonesia IPMG	Japan JPMA	Korea KRPIA	Malaysia PhAMA	Philippines PHAP	Singapore SAPI	Taiwan IRPMA	Thailand PReMA
IND/CTA	Requirements of the applicant	CRO is possible?	Companies or regulatory agency (CRO)	Basically, CRO and doctors who can follow standards of GCP.	Sponsor companies, CROs and doctors who can follow standards of GCP.	CRO , Companies and doctors who can follow standards of GCP.	Basically, companies and doctors who can follow standards of GCP.	Yes. Company, CRO or doctor, who can follow standards of GCP, can be IND holder.	An investigator, or an authorised person from a locally registered pharmaceutical company/ sponsor/ Contract Research Organisation (CRO) with a permanent address in Malaysia can make the application.	As per A.O. 2014-0034, a license is required for a Contract Research Organization (CRO) and its sponsor, prior to the conduct of clincial trial. Sponsor companies, CROs and doctors who can follow standards of GCP.	Sponsor company should make the application.	CRO can be an applicant, just the company **has to be registered as a pharmaceutical company in Taiwan.**	Drug manufacturing/import license holder or government (applicant can be sponsor or CRO
	Clinical trial consultation system	System, Timing, Procedure	**Public comments for revised version of draft consultation system have been requested in Dec. 18th 2015.** **1) I class meeting : Meeting for critical problem and/or severe problem for safety for innovative new drug, II class meeting : Among innovative drugs, ①Before PhI,②After PhII/before phIII, ③Before NDA, ④Before approval, III class meeting : Other meetings than class I and class II meetings.** **2) Timing of the meetings ; I class : within 30 days after submission, II class : within 60 days after submission, III class : within 75 days after submission** **3) Meeting form : Face-to-face meeting, record the minutes, CDE video recording** **Informal meeeting: Window for Applicant, tel, fax, e-mail, letter, TV etc. Do not discuss about conclusion regarding critical technical problem** **According to the formal CFDA opinions on priority review and approval issued on Feb 26 of 2016, as for new drug IND, it allows applicant to apply for communication with CDE before IND submission (1) Before Ph I, (2)After PhII/before phIII . However, the detail procedure has not been published.**	No	Non-formal consultation is possible. Pre-screening of the application is done at DCGI office before accepting our application. 1. IND- For phase 1 trials of NCEs application is referred to IND committee scheduled to meet every quarter. For molecule discovered outside India FIM studies are not permitted. 2. Other IND application -The application is referred to Subject Expert Committee(SEC) for review. Post review, the Sponsor/CRO is invited to a face to face meeting with SEC where they need to present & defend the proposal.	The consultation with Head of evaluator is available on every Tuesday and consultation with Assistant Director of registration is available on every Wednesday or by appointment .	There are many kinds of charged consultation with PMDA. Ex. Pre-PhI/Pre-PhIIa/Pre-PhIIb/EndofPhII study, Pre-application, Quality, Safety, etc. Flow: Tentative application (-8Week), submit the questions and documents (-5W), Inquiries and the answers, PMDA' opinion(<-4day), FtoF meeting, Fixed minutes (30days)	There are official and unofficial consultation system in Korea. Official pre IND consultation can be held 40 days before expected consultation meeting and it should be requested in written form. Meeting minutes will be issued 10 days after the meeting by MFDS(Ministry of Food and Drug Safety). Pre-review system covers IND preparations. F2F meeting 14~24 days after primary review result.	**A formal and structured consultation system is currently not in place but consultation may be requested on an informal basis.**	For company-initiated local trial, the proposed clinical trial protocol is prepared by the medical department in consultation with a physician-specialist who becomes a co-author. The protocol is then submitted to the GSB and regional Safety Department & Regulatory Department for approval. The final approval comes from the FDA. For investigator-initiated trials, the proposed protocol is written by the authors subject to the approval of the medical dept of HI-Eisai. (see FDA Circular 2012-007)	No. But for first-in-human trials, HSA would prefer if company has a pre-submission consultation about 2 months before submission.	Regulation consultation service is available for all phases of product development. It is free of charge without legal binding. Sponsors can choose official letter correspondence face to face meeting – to conduct the consultation. The procedure for face to face meeting should be on-line submission first. Then the project manager of CDE will contact with the applicant for confirm the question which applicant raised and requesting more information. 2 to 4 weeks after the submission will be taken for meeting arrangement. Also the project manager will arrange the appropriate time and attendee list for the consultation meeting. In general, 1 hour for FTF meeting, and meeting minutes may be available 2 weeks after the meeting.	Can consult at FDA (Such as direct contact, telephone)
	Flow of clinical trial notification, IND application and IRB permission	Flowchart	**Clinical trial can be initiated after IND approval, IRB permission, clinical research management committee permission(actually not implemented), ministry of science and technology permisson. In China, clinical trial application is required.** **For BE study, notification system is applied from Dec.01,2015 and for other studies, CTA system is applied**	Approval by DOH is required. IRB approval is also required.	Clinical trial on new drug shall be initiated after authorization by CDSCO (NOC:No Objection Certificate from DCGI) and approval of respective EC. In case of parallel applications, CDCSO will grant conditional approval and note that the trial should start after Ethics approval.	Flow Chart of Clinical Trial Notification see Attachment II a & II b , IIIa & IIIb , IV a & IV b. (See Annex 1)	In Japan, a clinical trial is conducted based on notification, not on application. Contracts with clinical sites should be signed after 30 days from the clinical trial notification (14 days from the second trial onwards).	There is no clinical trial notification system, and only IND approval is available. Clinical trial should be conducted within 2 years after IND approval. (See the flow chart at Annex 2)	A Clinical Trial Import Licence (CTIL) authorising the licensee to import a product for purposes of clinical trials is required. The sponsor/ investigator shall not start the clinical trial until the ethics committee/ Institutional Review Board has issued a favourable opinion and approved by the Drug Control Authority (DCA). All the clinical trials that require CTIL/ CTX (Clinical Trial Exemption) must be registered with NMRR (National Medical Research Register). NPCB will only accept favourable opinion/ approval issued by EC that is registered with the DCA.	We now have a central ethical review board in the FDA. This board reviews the protocol. Once approved, the CT may proceed. Centers where the clinical trial is to be conducted is notified. Please see FDA Circular 2012-007 (p. 6 &8)	Approval by HSA and IRB approval are required respectively before start of clinical trial. Parallel submissions is possible to both the HSA and the respective IRB.	TFDA has clinical trial notification (CTN) process and general IND application procedure. CTN process only reviews the administration documents by CDE without scientific review for protocol. IRB permission will depend on the site requirement and approval time also depends on IRB. Most contracts with clinical sites need to get IRB approval first prior to sign the contract, the time for contract may take around 2 months.	Same. Except the Guideline on Application for Drug Import permit into Thailand for Clinical Trial was updated since Aug 2015

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IND/CTA	Time required for clinical trial notification, IND application and IRB permission obtainment	Official timeline: (working days) Timeline based on actual experience	**Based on RDPAC timeline survey results in 2015, IND review and approval usually takes 16-22 months, IDL-CTA needs 36-48 months.** **State Councial released the reform plan in Aug.2015. There is a trend of shortening of the review time.** **Applicant should start clinical trial study within 3 years after geeting IND approval. If oerdue, permission will be invalid.**	3 months	IND review: 6-8 months EC review: 2-4 months	Timeline for evaluation is 14 working days for protocol & amendment of clinical trial after NADFC stated the protocol & amendment complete .	The rule of "after 30 days from the first clinical trial notification" for drugs containing new active ingredients, new ethical combination drugs and drugs with a new administrative route. The clinical trial can be started after 14 days from clinical trial notification for the second trial onwards (for the same product).	IND application official timeline based on the results of the consultation: 30 working days Timeline based on actual experience: Given 1 time query by MFDS during their IND review period, it takes 2-3 months. According to sites, IRB review will be held every 2 weeks to every 2 months depending on the sites. Totally, for initial 3 months, we can get IND approval & IRB approval in parallel.	Official Timeline for CTIL/CTX: 45 working days **for phase I trial, clinical trial involves biological/ biotechnological, cell therapy product and gene therapy product as well as herbal product.** For Others: 30 working days **The IRB/IEC should review a proposed clinical trial within a reasonable time.** Ethics approval: complete submission without queries can be approved within 4 to 8 weeks. **(Re Edition 6.1 Malaysian Guideline for Application of CTIL & CTX, NPCB)**	No specific timelines for trial notification. (Basically not more than 60 days from submission)	HSA review 4-6 weeks (30 days), CTT/IRB review 30-60 days.	The time for (CTA-Clinical Trial application) will be within 30 days. General IND application procedure will review protocol in detail by CDE and may request to revise protocol based on their review result. the approved time may take around 30 working days. **If the protocol is simontaneous submission in US FDA and / or EMA, fask track review is available so that the overall review time can be reduced as short as 14 days.** IRB permission time depends. The approval time may take around 3-4 months in average.	IND notification : (to Thai FDA) - 20 days IND : (to Thai FDA) - 20-60 working days IRB : (each study site or EC of MOPH) - institute EC 2-3 months/ EC-MOPH 6 months
IND/CTA application materials	Application form	Requirements and language	Yes : application form (in Chinese)	Application form for Certificate for Clinical Trial	Yes (Form 44, in English)	There is a checklist requirement .	Yes: Clinical trial notification form (in Japanese)	Yes: Clinical Plan Approval Request form (in Korean)	Application form for CTIL/CTX (Clinical Trial Import Licence/ Clinical Trial Exemption). In English or Bahasa Malaysia	Yes, in English. Please see FDA Circular 2012-007	Application form for Clinical Trial Certificate (CTC) to HSA. IRB has no form.	Application form is needed and it can be in English. But the format is in Chinese.	Local form (in Thai)
	A statement regarding the reason why the sponsoring of the proposed clinical trial is scientifically justified	Requirements and language	Yes (in Chinese)	No	Yes (in English) and vernacular language	Yes	Yes (in Japanese)	Yes (in Korean)	No	Please see FDA Circular 2012-007 (p.4)	No	Yes, the official letter to indicate the sponsoring of proposed clinical trial is needed.	Cover letter (have template in Thai)
	Protocol	Requirements and language	Yes (in Chinese）	Yes, in English	Yes (in English)	Yes	Yes (in Japanese）	Yes (in Korean)and all data	Yes, in English or Bahasa Malaysia Malaysian Guideline for Application of CTIL & CTX, Edition **6.1 September 2015) and all data must be in English or Bahasa Melayu**	Yes, in English	Yes, in English	**Required. Both Chinese or English version are acceptable.**	See detail in guideline, can be in Thai or English
	IB	Requirements and language	Yes (in Chinese) Usually synopsis or abstract of each report in Chinese is required, attached with source report.	Yes, in English For Ph IV trials, HK registered pack insert can be used.	Yes (in English)	Yes, (in Indonesian or English)	Yes (in Japanese)	Yes (English acceptable)	Yes,in English or Bahasa Malaysia. For content and format of the IB, reference is made to section 7, current version of Malaysian Guideline for GCP.	Yes, in English	Yes, in English	**Required. Both Chinese or English version are acceptable.**	See detail in guideline (for unregistered drug in Thailand)
	CRF (sample)	Requirements and language	MRCT: Yes (in Chinese) Import product: No	Yes, in English	Yes (in English)	Yes, (in Indonesian or English)	No, if the description of CRF is to be read by PC.	Yes (English acceptable)	Yes, in English or Bahasa Malaysia	Yes, in English	Yes, in English	**Required. Both Chinese or English version are acceptable.**	No requirement

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IND/CTA application materials	Informed consent	Requirements and language	MRCT: Yes (in Chinese) Import product: No	Yes, in English or Chinese	Yes- ENGLISH to be submitted to DCGI. ICF in local regional languages has to be submitted to Ethics committee for EC approval. (in a language that is non-technical and understandable by the study subject.)	Yes, (in Indonesian or English)	Yes (in Japanese)	Yes (in Korean)	Requirements as in 1. Malaysian Guideline for Good Clinical Practice, section 4.8 Informed Consent of Trial Subjects: 2. Malaysian Guideline for Application of CTIL and CTX, section 4.4.12 Informed consent form (Initial version only): The informed consent form (ICF) provided can be in either English or Bahasa Melayu.	Yes, in English	Yes, in English	Required. Should be in traditional Chinese.	Yes, in Thai
	Investigator's CV	Requirements and language	No	CV of PI	Yes (in English)	Yes, (in Indonesian or English)	No	No	The GCP certificate and CV for investigator/ PI of each trial site should be provided. The GCP course should be recognised/ approved by National Committee for Clinical Research (NCCR), Ministry of Health Malaysia. The requirement is in accordance to the current version of Malaysian Guidelines for GCP. in English or Bahasa Malaysia	Yes, in English PI of abroad in case of groval trial statement of PI	CV of PI, in English	**Required for both PI and Co-I. Both Chinese or English version are acceptable.**	No requirement
	Non-clinical summary	Requirements and language	Yes (in Chinese)	No	Yes (in English)	Yes, (in Indonesian or English)	No	Yes (in Korean)	Investigator's brochure in English or Bahasa Malaysia	Yes, in English	No	**No separate document is required. Referred to IB.**	including in IB
	Non-clinical report	Requirements and language	Yes (in Chinese) Usually synopsis or abstract of each report in Chinese is required, attached with source report.	No	Yes (in English)	Yes, (in Indonesian or English)	No	Yes (English acceptable)	Investigator's brochure in English or Bahasa Malaysia	Yes, in English	No	**No separate document is required. Referred to IB.**	including in IB
	Clinical summary	Requirements and language	Yes (in Chinese)	No	Yes (in English)	Yes, (in Indonesian or English)	No	Yes (in Korean)	No	Yes, in English	No	**No separate document is required. Referred to IB.**	including in IB
	Clinical report	Requirements and language	Yes (in Chinese) Usually synopsis or abstract of each report in Chinese is required, attached with source report.	No	Yes (in English)	Yes, (in Indonesian or English)	No	Yes (English acceptable)	Published clinical data in English or Bahasa Malaysia	Yes, in English	No (for HSA, every 6 monthly, status report of the trial to be submitted; for IRB usually annually)	Not required.	including in IB
	CMC summary	Requirements and language	Yes (in Chinese)	No	Yes (in English)	Yes, (in Indonesian or English)	No	Yes (in Korean)	Yes	Yes, in English	No	Required. English version is acceptable. **TFDA announced guidance of CMC requirement of Investigational new drug on November 2, 2015.**	See detail in guideline (for NCE)
	CMC report	Requirements and language	Yes (in Chinese)	No	Yes (in English)	Yes, (in Indonesian or English)	No	Yes (English acceptable)	Yes	Yes, in English	No	Not required.	See detail in guideline (for NCE)
	GMP certificate of the investigational drug	Necessary or Unnecessary	**For IND of IMCT, GMP certificate is not required. But a statement that investigational products are formulated in accordance with GMP should be submitted; For CTA of import drug , CPP with GMP statement is required; For CTA of domestic drug, hard copy of GMP certificate of manufacturing plant is required.**	Yes	YES	Yes, (in Indonesian or English)	No	Necessary	Yes, **necessary.**	Yes, in English COA of investigational drug,	No (HSA application, to provide GMP certificate of the Drug Product site of Investigation drug, during CTC application)	**GMP certificate of the investigational drug is NOT mandatory.**	Necessary

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IND /CTA appliation materials	Sample of the investigational drug (for IND review)	Requirements and language	Yes for import product registration.	Yes, proposed label and COA also.	Samples of reference standards and finished product (equivalent of 50 clinical doses or more, if requested by the Authority), with testing Protocol/s, full impurity profile and release specifications. DCGI normaly asks the applicant to submit the samples of the drug product along with reference standard to the government laboratory (Central Drug Testing Laboratory or Indian Pharmacopoeial commission Laboratory). The Applicant needs to submit the samples in the quantity sufficient for three fold analysis.	No	No	No	No, COA only.	Yes (Laboratory testing may be requested)	No	Not required.	No requirement

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NDA	Acceptance of CTD format	CTD or ACTD or Others ?	CTD of CMC for chemical drug with registration category 3~6 can be acceptable. CTD of non-clinical, clinical documents are not acceptable at this moment. CTD of biologicals are still not acceptable.	Not specified. CTD can be accepted.	ICH-CTD is acceptable. However, it is not indicated in document issued by HA.	ACTD format.	Application data for new drugs have to be handled by the CTD format.	CTD format is required for NCE (New Chemical Entity), IMD(Incrementally Modified Drug) and generic drugs requiring BE(Bioequivalence) test data.	All applications are made in ASEAN CTD format.	Application data for new drugs have to be handled by the ASEAN CTD format. There is flexibility on the use of ICH dossier as per FDA Adoption of ACTD.	ACTD or ICH-CTD	Application for NCE/BLA have to be submitted in CTD format.	ACTD ICH-CTD is accepted only for NCE and Biotech products. ACTD-mapping documents shoule be submitted.
	Category of NDA	ex. NCE, Generic, Supplemental,	New registration categories for chemical drugs are issued on Mar.04,2016. 1.Innovative drugs not marketed in and outside China. Drug substances and their preparations containing new compounds with definite structure and pharmacological actions and possessing clinical value. 2.Improved new drugs not marketed in and outside China 2.1 Drug substances and their preparations containing optical isomers with known active ingredients made through such methods as resolution or synthesis, or esterification of known active ingredients, or saltification of known active ingredients (including salts containing hydrogen bond or coordinate bond), or the alteration of the acid radicals, basic groups or metal elements, or the formation of other non-covalent bond derivatives (complex, chelate or clathrate) and possessing significant clinical advantages ii. Preparations of new dosage forms containing known active ingredients (including new administration systems), new formulation and manufacturing processes, new routes of administration and possessing significant clinical advantages. 2.2 Preparations of new dosage forms containing known active ingredients (including new administration systems), new formulation and manufacturing processes, new routes of administration and possessing significant clinical advantages. 2.3 New compound preparations containing known active ingredients and possessing significant clinical advantages. 2.4 Preparations of new indications containing known active ingredients 3.Drugs generic to original drugs marketed overseas yet not marketed in China 4.Drugs generic to original drugs marketed in China 5.Applications of drugs marketed overseas for marketing in China 5.1 Applications of original drugs marketed overseas (including drug substances and their preparations) for marketing in China 5.2 Applications of non-original drugs marketed overseas (including drug substances and their preparations) for marketing in China	Two categories: 1. New Chemical Entity (NCE); 2. Generic (i.e. drug substance already registered at Department of Health (DOH))	New Drug: 1) New Chemical Entity (NCE), 2) New indications, dosage, dosage form and route of administration 3) Fixed Dose Combination (FDC) (See 122E of the Drugs and Cosmetics Rule) Note: all vaccines and Recombinant DNA (r-DNA) derived drugs shall be new drugs unless certified otherwise by the Licensing Authority	A. New Registration consist of : a. Category 1: New Drug and Biological Product registration including Biosimilar Product. b. Category 2: copy drug / generic product. c. Category 3: Registration of other dosage form. B. Registration of drug variation, consist of : a. Category 4: Major variation registration (VaMa) b. Category 5 : Minor variation registration that needs an approval (VaMi-B) c Category 6.: Minor variation registration with notification (VaMa-A) C. Renewal a. Category 7: Renewal .	(1) Drugs containing new active ingredients (2) New ethical combination drugs (3) Druds with a new administration route (4) Drugs with a new indication (5) New dosage form drugs (6) New dosage drugs (7) Follow-on biologics (8) Drugs supplied in an additional dosage form (9) Similar ethical combination drugs (10) Other drugs (Minor changes in approved matters are handled by simply submitting notices.)	<Chemical> (1) New Drug 1) New chemical structure (NCE) 2) Combination drug including NCE (2) Data requiring drug (Drug for supplementary data submission) 1) Drug with new salt or isomer, etc. 2) Drug with a new indication 3) New dosage drug - Increase/Decrease amount of API - New combination drug 4) Drug with a new adminstration route 5) Drug with a new dosage and administration 6) Enzyme, yeast, microorganism derivated drug with new origins 7) Drug with a new formulation(same route of administration) <Biologics> (1) Drug containing new molecular entities 1) DNA recombinant durg and Cell culture drug 2) Biologics - Vaccine, antitoxins - Blood products - Biologics other than above (therapeutic antigens, botilinium products, ect). (2) Data requiring drug(Drug for supplementary data submission) 1) Biologics : strains and manufacturing methods are different from authorized biologics 2) Recombinant DNA products: hosts, vectors, or methods to obtain DNA is different from authorized biologics 3) Cell culture derived products: same cell line, but different cell culture or purification methods from authorized biologics 4) Cell culture derived product: cell line is different from authorized biologics 5) When final bulk is the same, but the site for manufacture is different 6) New dosage forms with the same route of administration 7) Biosimilar product(recombinat DNA) 8) Total plasma and component preparations 9) Others not separately classified	Drug Registration Guidance Document (DRGD) Section A, 1.2 Categories Of Product : 1) New Drug Products a) New Chemical Entity (NCE)/ Radiopharmaceutical Substance b) New Combination Product c) Supplemental Product 2) Biologics 3) Generics 4) Health Supplements 5) Natural Products	(1) Drugs containing new active ingredients (2) New ethical combination drugs (3) Drugs with a new administration route (4) Drugs with a new indication (5) New dosage form drugs (6) New dosage drugs (7) Follow-on biologics (8) Drugs supplied in an additional dosage form (9) Similar ethical combination drugs (10) Other drugs	NDA-1 for the first strength NCE and biological entity. NDA-2 for new combination, new dosage form, new route of administration or new indication of registered chemical entities. NDA-3 for subsequent strengths of a new drug product. GDA-1 for the first strength of a generic chemical product. GDA-2 for subsequent strenths of the generic chemical product.	New Drug I : (1) New chemical entity (2) New indication (3) New combination (4) New administration route New Drug 2 (1) New dosage form (2) New usage dose (3) New unit dose	1) Chemical drugs 1.1) New Drugs (NCE, NI, NCO, ND, NR, NDOS, NS) 1.2) New Generic (NG) 1.3) Generic (G) 2) Biological Products *NCE = New Chemical Entity, NI = New Indication, NCO = New Combination, ND = New Delivery system, NR = New Route of administration, NDOS = New Dosage form of Approved New Drug, NS = New Strength of Approved New Drug

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NDA	Requirement of CPP	Timing of submission. ex. at NDA, before approval Number of required CPP. Source country. ex. Manufacturing/exporting country, Marketing country (FSC)	Cat. 1 Import drug require CPP at NDA. Both CPP granted by manufacturing country or marketing country are acceptable.	To be submitted at the time of application No. of CPP required: NCE: 2 ICH countries Generic: 1 (source country only)	CPP or Free sale certificate (FSC) issued by country of origin is required at NDA. The CPP and FSC should be notarised and apostilled or legalised by Indian embassy of the country of origin.	Copy CPP is submitted during pre-registration. The original CPP should be present during registration. CPP only required for imported product. The product with one CPP will be evaluated within 300 working days . The product with three CPP + **two Assessment Report from Other Health Authority** (one CPP from manufacturing country , two CPPs from EU, US, AUS, UK) will be evaluated within 150 working days.	Not required	Required for **NDA and some variations (e.g. addition of DP manufacturer) of** Import Drugs Timing : Before approval Number : One original document **or legalized (apostilled) copy** Source : Manufacturing country/Marketing country (**For the manufacturing country, the GMP certificate can replace the CPP.**)	Category 1 & 2: CPP required at time of application; Category 3: CPP required at time of application but not required for locally produced generics; CPP from the competent authority in the country of origin; or GMP Certification/ Manufacturing License for the manufacturer from the relevant competent authority, together with CPP from the country of the product owner; or CPP from country of release, if CPP from the country of the product owner is not available)	Timing of submission is at NDA. Number of required CPP is 1 from Source country e.g. ex. Manufacturing/exporting country, Marketing country (CPP or FSC/GMP) or any reference country	Submission of CPP is not compulsory and depends on type of submission. In case a bridge of NDA product, proof of approval by any drug regulatory agency is required.	CPP(s) are required before NDA approval. 2 CPPs from 10 advanced countries are required for NCE/BLA approval if no clinical studies in Taiwan. At the time of filing, NCE/BLA can be submitted without CPP. When approaching approval time, if Taiwan participates two global clinical trials (Ph1+Ph3 or Ph2+ Ph3) with desigante numbers of Taiwan subjects enrolled, (Clinical development in Taiwan in earlier) then CPP can be waived. NCE/BLA can be approved with one CPP in one of 10 advanced countries but also need one clinical trial in Taiwan (Ph1 or Ph2 or Ph3) with desigante number *of* Taiwan subjects enrolled into the study. 1 EMA CPP accounts for approvals in 5 advanced countries. Product have to be launched in source country or 10 advanced countries.	At NDA submission 1 original CPP Manufacturing country
	Approval can be obtained by utilizing foreign clinical trial data.	Requirement of bridging data/report and global clinical trial data/report. Necessity of PK study in local population.	Global / MRCT clinical data for chemical drugs are acceptable, but Chinese P3 and PK data is indispensable. There are also Chinese samples size requirements at the same time. For biologicals, global / MRCT clinical data is **acceptable. For imported pediatric drugs in clinical needs and already marketed in the United States, the European Union and neighboring regions of China, relevant clinical trial data completed overseas may be used for the drug registration applications in China.(from CFDA opinion on implementing priority review and approval to resolve the backlog of drug registration applications on Feb 26, 2016.)**	The overseas clinical trial data is acceptable. Bridging data are not required.	Clinical data in Indian population is required except few life saving therapeutic categories which is at the discretion of the regulatory agency. However now a days, DCGI has become very strict and insists for local clinical trial data for every new drug.	Overseas clinical trial data is acceptable, as long as it is aligned with ICH and/or WHO guideline. Local regulatory trials is required for **TB program** and drug for family planning program /	The overseas clinical trial data is accepted in accordance with ICH E5. The drugs approved by using a bridging strategy or global clinical trial data have increased. But Japanese PK data is indispensable. **Discussion of ICH E17 is ongoing.**	Only for New Drugs, bridging data is needed additionally. (See figures at Annex 3)	Overseas clinical trial data is acceptable, as long as it is aligned with ICH and/or WHO guidance, and accepted by the major reference countries. Local regulatory trials are not required.	The overseas clinical trial data is accepted.	Overseas clinical trial data is acceptable	The overseas clinical trial data are accepted in accordance with ICH E5. BSE is mandatory for NCE NDA. Complete clinical data package relevant to the Asian population is required to BSE. Bridging study is generally required when there is ethnic difference. A bridging study is to provide clinical data of pharmacokinetic / pharmacodynamic or clinical data on efficacy, safety, dosage and dose regimen in Taiwan that will allow extrapolation of the foreign clinical data to different populations. Taiwanese PK may be waived through BSE submission. Some time may needs Taiwan PK or PD or dose-response data, it depends on the product. The product with ethical difference may needs Taiwan local PK or PD data to support NDA approval.	Not required

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NDA	Application fees	Fees necessary for applying for approval as for NME drug with full data (Category (1))	▪**Registration fee: NDA: 432,000 RMB (local drug)** **593,900RMB(import drug)** **Authorities comment: Application fee gap between the import drug and local drag are due to the difference in the inspection cost.**	Application fee: HKD 1100 License fee: HKD 1370 Renewal fee (every 5 years): HKD 575	**Structure remains the same, but draft proposal to increase the same by 3 to 4 times has been proposed.** Application fees: NDA: INR 50000 (include MAA fee) Import License: Rs 1000 and at the rate of Rs.100/- for additional drug. Registration Certificate (for import drug): 1500USD for one manufacturing site or its equivalent in Indian currency and 1000USD for one drug or its equivalent in Indian currency. An additional fee at the rate of one thousand US dollars for each additional drug. Duplicate Registration certificate: three hundred US dollars shall be paid for a duplicate copy of the Registration Certificate, if the original is defaced, damaged or lost. Inspection Fee: The applicant shall be liable for the payment of a fee of five thousand US dollars for expenditure as may be required for inspection or visit of the manufacturing premises or drugs, by the licensing authority Test License:The fee of import licences for test and analysis of a drug has been kept Rs. 100 for a single drug and at the rate of Rs. 50/- for each additional drug	Application fee : Pre-Registration : 1 Million IDR (MIDL) Registration fee for : Category 1 : new product & Biological Product : 30 MIDR, new indication : 20 MIDR Category 2: copy product 7.5 MIDR, copy product with BA/BE data: 12.5 MIDR Category 3 : other product: 7.5 MIDR Category 4: VaMa : 2 MIDR for each dosage form/packaging Category 5: VaMa-B : 2 MIDR for each dosage form/packaging. Category 6: VaMi-A : 1 MIDR for each dosage form/packaging. Category 7: renewal : 5 MIDR For pre-inspection GMP document: 7.5 MIDR. For GMP site inspection: three inspector three day = 90 MIDR	Application fees of drugs containing new active ingredients To Government : 533,800 yen To PMDA for review : 23,788,100 yen for paper-based compliance inspection : 6,747,000yen for GCP inspection : domestic 2,801,000 yen, overseas 3,098,000 yen +Travel expense for GMP inspection : domestic 760,900 yen, overseas 960,200 yen +Travel expense	Application fee (1) Chemical : NCE for review : 3,726,000 KRW (STM review + S&E review + GMP review) (2) Biologics : NME for review : 3,726,000 KRW (STM review + S&E review + GMP review) (3) **Orphan drugs : 2,895,000 KRW** (4) **Other NDAs including** Biosimilar for review : 1,134,000 KRW (STM review + S&E review + GMP review) for GMP/GCP inspection(around 7,500,000KRW/person(overseas)) : This one is the travel expense for inspectors, so if GMP inspection would be waived, no more fee is needed. cf. Generics: KRW 720,000(BE, CMC, GMP review included)	**Fees are required and details are given in the DRGD Appendix 1: Fees.These are according to product categories, number of active ingredients, types of applications etc.**	NCE: 900 USD Initial Registration: 340 USD (1USD= 45 PhP) * above rates are current; however these may change pending implementation of proposed new revised fees.	Screening Fees: Abridged/verification $550 Full dossier: $2,750 Evaluation Fees: NDA-1 & NDA-2 (abridged): $11,000, NDA-3 (abridged): $5,500 NDA-1 & NDA-2 (verification): $16,500 NDA-3 (verification): $5,500 NDA full dossier: $82,500 GDA-1 (abridged): $3,850 GDA-2 (abridged): $2,200 GDA-1 (verification): $10,000 GDA-2 (verification): $5,000	NDA: Application fees (the charge fee is amended on **May 13, 2015,** "Fee-Charging Standards for the Registration of Western Medicines and Medical Devices") 1. Product registration of a new drug which is of new active pharmaceutical ingredient(s), **including new biological drugs / genetical engineering drugs**: NT**800,000.** 2. Product registration of a new drug which is of new **combination** or new administration route: NT**300,000.** 3. Product registration of a new drug which is of a new dosage form, new strength with new indication, new dose unit, or controlled release dosage form, new strength of the same therapeutic compound(s) and the same administration route: NT**150,000.** GMP Inspections for Western Medicines: 1. GMP Inspections for domestic pharmaceutical manufacturers which is new establishment, relocation, expansion, resumption of operations, or addition of a new active pharmaceutical ingredient, dosage form, process operation, medicinal product: NT**120,000;** Additional fee of NT20,000 will be charged whenever there is an additional dosage form, biological drug, or active pharmaceutical ingredient. 2. GMP Inspections for foreign pharmaceutical manufacturers 1. Review of a Plant Master File (PMF) of an foreign pharmaceutical manufacturer: NT**120,000**; Additional fee of NT20,000 will be charged whenever there is an additional dosage form, biological drug, or active pharmaceutical ingredient. **New foreign manufacturing site overseas on-site inspection: NT700,000 or above.**	Not required 2,000 baht (pay after approval)
	Other requirements		It's mandatory to follow 3submissions-3approvals regulation in drug applications using IMCT data .		Application for Import License is required after marketing approval and Registration Certificate	Specific country requirement on product labeling on product package, example: generic name, retail price, symbol of prescription drug, the name of importer. Site Master File is requested for non registered oversea factories at submission. Inspection may be conducted against oversea factories if necessary.		For the NDA of a New Drug, i) Safety & Efficacy **ii) Quality (including Specification** and Test Method) iii) GMP iv) DMF reiviws are mandatory		Reference Standard Sample (at least 300 mg) subject to FDA advise	For GDA, the reference product must be the registered product with Singapore HSA	N/A	

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NDA application materials	CMC summary	Requirements and language	Yes (Chinese)	for NCE only (document in English)	Yes, in English	Yes (in Indonesian or English as in part II Quality)	Yes (in Japanese as M2 in CTD)	Yes (M2 in CTD, Korean)	Yes (Part 2 in ACTD) - in English or Bahasa Malaysia	Yes,ACTD Part II in English	Yes (in English) Singapore Quality Overall Summary(SQOS) is required.	Yes (In English as M2 in CTD) **For the new drug application, TFDA requires to include the API information in detail. API DMF is required.**	Requirement, see ACTD of new drug registration part II / Eng
	CMC report/body of data	Requirements and language	Yes (Chinese)	for NCE only (document in English)	Yes (English is acceptable as M3 in CTD)	Yes (in Indonesian or English as in part II Quality)	Yes (English is acceptable as M3 in CTD)	Yes (M3 in CTD, English is acceptable, but spec.and test methods **for DP and DS with non-pharmacopeial spec.** should be prepared in Korean in Application package.)	Yes - in full (Part 2 in ACTD) - in English or Bahasa Malaysia	Yes,ACTD Part II in English	Yes (in English)	Yes (In English as M3 in CTD) **For the new drug application, TFDA requires to include the API information in detail.**	Requirement, see ACTD of new drug registration part II / Eng
	Non-clinical summary	Requirements and language	Yes (Chinese)	for NCE only (document in English)	Yes, in English	Yes (in Indonesian or English as in part III Non Clinical Data)	Yes (in Japanese as M2 in CTD)	Yes (M2 in CTD, Korean)	Yes (Part 3 in ACTD) - in English or Bahasa Malaysia	Yes,ACTD Part III in English	Only for full dossier, in English	Yes (In English as M2 in CTD)	Requirement, see ACTD of new drug registration part III / Eng
	Non-clinical report	Requirements and language	Yes (Chinese) Usually synopsis or abstract of each report in Chinese is required, attached with source report.	for NCE only (document in English)	Yes (English is acceptable as M4 in CTD)	Yes (in Indonesian or English as in part III Non Clinical Data)	Yes (English is acceptable as M4 in CTD)	Yes (M4 in CTD, English is acceptable)	Yes (Part 3 in ACTD) - in English or Bahasa Malaysia	Yes,ACTD Part III in English	Only for full dossier, in English	Yes. (In English as M4 in CTD)	Requirement, see ACTD of new drug registration part III / Eng
	Clinical summary	Requirements and language	Yes (Chinese)	for NCE only (document in English)	Yes, in English	Yes (in Indonesian or English as in part IV Clinical Data))	Yes (in Japanese as M2 in CTD)	Yes (M2 in CTD, Korean)	Yes (Part 4 in ACTD) - in English or Bahasa Malaysia	Yes,ACTD Part IV in English	Yes (in English)	Yes. (In English as M2 in CTD)	Requirement, see ACTD of new drug registration part IV / Eng
	Clinical report	Requirements and language	Yes (Chinese) Usually synopsis or abstract of each report in Chinese is required, attached with source report.	for NCE only (document in English)	Yes (English is acceptable as M5 in CTD)	Yes (in Indonesian or English as in part IV Clinical Data). Indonesia required full clinical study report	Yes (English is acceptable as M5 in CTD)	Yes (M5 in CTD, English is acceptable)	Yes (Part 4 in ACTD) - in English or Bahasa Malaysia	Yes,ACTD Part IV in English	Yes (in English)	Yes. (In English as M5 in CTD)	Requirement, see ACTD of new drug registration part IV / Eng

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NDA application materials	Other required documents	Requirements and language	Application form Summary part of application dossiers: (1) Name of the drug (2) Certified Documents, including CPP etc. (3) Objectives and basis for development (4) Summary of CMC, Non-clinical and clinical (5) packaging insert and its reasons, and latest references (6) artwork and labeling	Needs to be in English. General requirement for product registration: 1. Authorization letter from manufacturer – to authorize HKOP register, import and market the product 2. Manufacturer license – original 3. CPP- original 4. Information on the manufacturing facilities and practices of the manufacturer & GMP Certificate **which meets PIC/S GMP standards** 5. Registration sample – color photos/scanned image to show the product and sales pack/container appearance. 6. Proposed sales pack – color prototype 7. Proposed pack insert - prototype - The following document(s) to support the proposed indication(s), dosage, route of administration and other contents of the package insert (if any): a. a copy of reputable reference b. documentary evidence showing that the package insert has been approved by one of the listed countries 8. Master formula (Batch formula not accepted) - Non-proprietary names of ingredients, colour Index number or E-number for all colourants used should be provided 9. Finished product specifications 10. Method of analysis 11. COA of a representative batch 12. Stability data 13. Bioequivalence data for anti-epileptic drugs The BE studies should be conducted in accordance with World Health Organization guidance on the "Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability" or other international guideline. 14. Safety documents for ingredients with animal origins Additional requirements for NCE registration 1. 2 ICH country approvals 2. expert evaluation reports on the safety, efficacy and quality of the product. CV of experts who draft the report. 3. EU-RMP and/or US-REMS, if applicable. Information on whether any risk management plan activities and mitigation strategies will be implemented in HK. 4. clinical and scientific documentation substantiating the safety and efficacy of the product.	AS described in Schedule Y of the Drugs and Cosmetics Rules 1945 1.1 Comprehensive table of contents (Modules 1 to 5) 1.2 Administrative information 1.2.1 Application in Form 44 and Treasury Challan (fee) 1.2.2 Legal and statutory documents 1.2.3 Coordinates related to the application 1.2.4 General information on drug product 1.2.5 Summary protocol of batch production and control 1.2.6 List of countries where MA or import permission for the said drug product is pending and the date of pendency. 1.2.7 List of countries where the drug product has been licensed and summary of approval conditions. 1.2.8 List of countries where the drug product is patented 1.2.9 Domestic price of the drug followed in the countries of origin in INR 1.2.10 A brief profile of the manufacturer's research activity 1.2.11 A brief profile of the manufacturer's business activity in domestic as well as global market. 1.2.12 Information about the expert(s)/ Information regarding involvement of experts, if any 1.2.13 Environmental risk assessment 1.2.14 Samples of drug product	See regulation No.HK.03.1.23.10.11. 08481fromBPOM regarding the Criteria and Procedure of Drug Registration.	CTD Part I (Module 1) in Japanese 1.1 Table of Contents 1.2 Approval application (copy) 1.3 Various certificates 1.4 Information on patent matters 1.5 Data concerning the origin or background of development 1.6 Information on the use of the drug in foreign countries 1.7 List of similar products from the same therapeutic category with the same efficacy 1.8 Package insert 1.9 Documents pertaining to the non-proprietary name of the drug 1.10 Summary of data pertaining to the designation as a poisonous drug, etc 1.11 Master plan for post-marketing surveillance 1.12 List of attached data 1.13 Other data	Module 1 1.1 Table of contents of Module 1 1.2 Application form or approval application(Copy) 1.3 Signature of the person in charge of preparation of CTD, His/Her information(career) 1.4 Certificate of translator 1.5 Information on the use of the applied drug in foreign countries 1.6 Information on comparison with other similar products available in the Korean market and properties of the applied drug 1.7 Various documents related to **Regulations on Safety of Pharmaceuticals Article 4 (1)** 1.7.1 Bioequivalence test data/ Dissolution test data 1.7.2 CPP 1.7.3 GMP data 1.7.4 DMF data 1.8 A contract(In case any process during manufacturing, QC test would be outsourced) 1.9 LTOC 1.10 Package insert(draft) 1.11 Other data	In English or Bahasa Malaysia: ACTD Part I :Administrative Data And Product Information Section A: Product Particulars Section B: Product Formula Section C: Particulars Of Packing Section D: Label (Mockup) For Immediate Container, Outer Carton And Proposed Package Insert Other admin doc: CPP, LOA, CA, GMP CERT	The following documents as ACTD part I (FDA Circular 2013-019) Sec.A Introfduction Sec.B Table of Contents Sec.C Administration data and Product Information 1 Application Form 2 LOA 3. Certificates For import product, a. License of pharmaceutical industry b. CPP c. SMF 4. Labeling 5. Product information 5.1 Package Insert 5.2 SmPC 5.3 PIL	Module 1 (or ACTD Part Ⅰ) documents e.g, Letter of authorizations Declarization Artwork of packaging material GMP certificate Patent declaration Reference country/product approval and approved package insert, if applicable	CTD Module 1 (Taiwan Specific) CTD formate was announced in July 2012 and became mendatory for NCE products since Nov. 01, 2012. New Drugs other than NCE, as well as generic products also need to be submitted in CTD format starting from July 01, 2014. 1 Administrative Information and Prescribing Information 1.1 Table of Contents of the Submission Including Module 1 1.2 Application Fee Receipt 1.3 Official Letter and Document 1.4 Application Form (original copy and duplicate copy) 1.5 Affidavit 1.6 Form for Sticking Label and Package Insert **TFDA requires to include the material and name of excipient in Prescribing Information.** 1.7 Certificate/License 1.8 Letter of Authorization 1.9 CPP of Source Country 1.10 Formulation Basis 1.11 Certificate of PIC/S GMP/cGMP 1.12 CPP 1.13 Bridging Study Evaluation 1.14 Status of Clinical Study Taiwan involved 1.15 Status of Bioavailability (BA)/ Bioequivalence (BE) Study Taiwan involved **TFDA partially updated the Guidance of Bioavailability (BA) and Bioequivalence (BE) Test on March 6th, 2015.** 1.16 Contract Manufacturing 1.17 Applications of Contract Analysis 1.18 Radiation Dosage Study Report 1.19 Risk Evaluation and Mitigation Strategy (REMS) 1.20 Other Documents or Reports	Requirement, see ACTD of new drug registration part I / Eng

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NDA Approval review	Review organization	Review organization, Decision organization, Advice committee	Review CDE (Center for Drug Evaluation) Decision CFDA (China Food & Drug Administration) Inspection Regional Drug Administration / Center for Food and Drug Inspection of CFDA	Review: Drug Office, DOH Approval: Pharmacy and Poisons Board	CDCSO/DCGI (Drug Control General of India) Twelve New Drug Advisory Committees (NDAC) were newly constituted to examine the applications for permissions for clinical trials and approvals for new drugs.	1. Committee of Safety-Efficacy Evaluation with the task of evaluating the safety and efficacy aspect to be discussed in the periodic meeting of National Committee/ KOMNAS. 2. National Committee on Drug Evaluation with the task of discussing formulating, giving consideration and decision of the results of drug evaluation through a periodic forum meeting. 3. Committee of Quality Evaluation with the task of evaluating the quality aspect. 4. Committee of Product Information Labeling Evaluation with the task of evaluating in the aspects of Product Information and Labeling.	Review PMDA (Pharmaceutical and Medical Device Agency) Decision MHLW (Ministry of Health, Labour and Welfare) Advice CDFS (Council on Drug and Food Sanitation)	MFDS and NiFDS(National Institute of Food and Drug Safety Evaluation) Advice : Central Pharmaceutical Affairs Council	National Pharmaceutical Control Bureau (NPCB): Receive and review applications; NPCB's Review Committee will finalise and propose it to the Drug Control Authority (DCA) for approval/rejection. DCA: decide on registrations & licenses, and new/revised regulatory requirements.	Philippines FDA Department of Health Food and Drug Administration	HSA (Panel of internal and external reviewers.)	Review center is composed of TFDA and CDE. Drug Advisory Committee provides consultation during the review and further endorses the CDE review if there are special issues. Decision organisation is TFDA.	Thai FDA
		Number of reviewers ex. Clinical, Non-clinical, CMC, Chemical/Biological	All staffs : 103 Traditional Chinese drug : 16 CMC : 28 Biologics : 9 Non-clinical : 13 Clinical : 21 Biostatistics : 3 Clerical work : 14 (As of Mar, 2015) **<2018 personnel plan>** **CDE : 500 in tatal for both IND/CTA and NDA.** **Provincial FDA : 300 (no clear information)**	Undisclosed	CDSCO total manpower 327 (as of 2009). No detailed information.		All staffs : **820** Review Dept. : **532** Safety Dept. : **165** (**As of Apr. 1, 2015**) Pharmacology : 384 Medical doctors and Dentists : 42 Engineering : 44 Veterinarian and Toxicity : 25 Biostatistics : 13 Science and agriculture, etc. : 63 Clerical work : 101 (As of April 1, 2012)	MFDS Chemical Administration - Drug policy: **28** **- Drug management: 16** GMP: **21** Clinical Trial Management: **17** Narcotics: **16** Bio Administration(Bio policy): **18** Bio GMP: 15 Traditional medicine: **9** **Patent Management: 8** **Safety Evaluation: 16** NiFDS Drug Review Management: **37** Pharmaceutical Standardization: **15** **Cardiovascular and Neurology products: 15** Oncology **and Antimicrobial products: 13** **Gastroenterology and Metabolism products: 12** Bioequivalence **Evaludation: 20** Biologics: **21** Recombinant **Products: 11** Cell & Gene Therapy: **13** Herbal medicines: **10** and Regional KFDAs	Total NPCB staff: ~500 Centre for Product Registration: ~120	All staffs : 400 FDA employees	GMP on-site inspection or PMF registration (paper review) is requested and the approval should be got then NDA can be approved accordingly. Otherwise NDA Approval will be held until GMP sttus confirmed (inspection or PMF approval). The GMP compliance check should be done by TFDA for each manufacturing site, even toll manufacture site or packaging site.	Division of Medicinal Products under TFDA, which is responsible for all drug products, has around 100 active staff including administrative, drug safety and regulation build-up. Among the menpower, about 40-50 staff belong to new drug, generic drug and clinical trial reviewing force.	See Attached sheet-Number of reviewers (Annex 8)

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NDA Approval review	Review process	Append the flow of the review of applications for new drug with the attached paper.	CFDA accepts the NDA application documents and transfer these documents to CDE in 30 work days, then CDE reviews and evaluates it in 150 working days after the application enter reviewing plan ,finally, CFDA approves it in 30 work days. CDE review process for IND/NDA is attached for reference. From 2014, CFDA started requesting additional clinical trial waiver application for import drugs after completion of MRCT and before NDA.	Undisclosed	DCGI accept the application in Form 44 and then it is forwarded to NDAC for expert review.	Pre-registration review document until complete documents --> Payment of pre-registration fees -->submit pre-registration --> Evaluation--> Approval Pre-Registration Registration review document --> Payment of registration fees --> Submit registration documents --> Clock start of registration review Note : * Only NCE/Biological Product Non-Clinical & Clinical were evaluated through Committee of Safety-Efficacy evaluation and National Committee then continue with Committee of Quality Evaluation , and Committee of Product Information. *Others (Generic & variation) were evaluated with Committee of Quality Evaluation , and Committee of Product Information.	See Annex 6	See figures at Annex 7	**See Annex 4 (Re DRGD 8. FLOW OF REGISTRATION PROCESS)**	Please see Flowchart_PSD_revised_Aug 2007 Submit to Center for Drug Regulation and Reseach (CDRR)	Screening/evaluation/queries, input requests/regulatory decision	See Annex 5	**Review process, see public manual of each NDA** Annex 9
	Review time	The standard period of time from acceptance of applications to the approval of new drugs.	Official timeline of CTA / NDA of import drug from submission to approval: 145 working days. **Based on RDPAC timeline survey results in 2015, IDL-NDA review and approval usually takes 24-30 months. After publication of the Opinions of the State Council（Aug 2015 No. 44 ）, review speed is rapidly up, especically for CTA applications with registration category 3.1 and BE application for generic drugs.** **In addition, CFDA issued the formal opinion on implementing priority review and approval to resolve the backlog of drug registration applications on Feb26, 2016. Within the application scope, the new drug NDA can benift to speed up review.**	NCE: 12-15 months Generic: 9-12 months	About 12-15 months for marketing approval and registration certificate. About 3 months for Import License.	Timeline of pre-registration 4 0 working days after completed documents for category 1,2,3,4,5.Timeline of registration 100 working days after completed documents for : a. New Drug & Biological Product that are indicated for the treatment of serious life-threatening human disease , or classify as Orphan drug, or classify for public health program, or new drug which development by Pharmaceutical industry / research institution in Indonesia b. New registration of generic essential copy drug. c. New registration of copy drug with standard electronically information (Stinel). d.Major variation . Timeline of registration 150 working days after completed documents for a New Drug , Biological Product , major variation with : 3 (three) CPP from countries with known good evaluation, system or approved in the country that has applied harmonized evaluation system (EU , EPAR, EMEA). b. New Registration of Copy Product without Stinel. Time line of registration of 300 working days after completed documents:1 CPP from original country.	Review time of FY **2014 (60 percentile)** Priority review products : **8.8** months Standard review products : **11.9** months	Practically around 12 months are needed for NDA	See DRGD Section 8.4.4 Timeline For Product Registration Eg: NCE/NBE: 245 Working days; Generics: 210 working days, etc	Review time of FY 2012 (Median) Priority review products : 9 months Standard review products : 15 months New lead time: 18 months	Screening: 25 working days Evaluation: Full dossier: 270 working days Abridged: 180 working days Verification: 60 working days	Review time Priority review products: 12 months standard review products: 18 months	**Timeframe for approval, see public manual of each NDA** **New drug - 280 working days** **Vaccine - 350 working days** **Generic and New Generic - 155 workign days** Annex 9

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NDA Approval review	Priority review system	Presence of priority review system, Content of system, Subject drug for priority review ex. unmet medical needs, for serious life-threatening disease	Special review procedure exists, which is appropriate for following applications of new drugs: 1) Active ingredients extracted from plants, animals or minerals, etc. and their preparations not yet marketed in China, and newly discovered Chinese crude drugs and their preparations; 2) Chemical drug substance and their preparations and biological products not yet approved for marketing in China or abroad; 3) New drugs for the treatment of diseases such as AIDS, malignant tumors and rare diseases, etc. with significant clinical advantages; and 4) New drugs for the treatment of diseases, for which effective therapeutic method is not available. For those drugs specified in items 1) & 2), the applicant of drug registration (hereinafter "the Applicant") may apply for the special examination and approval when submitting the application for clinical trials of the new drugs. For those drugs specified in items 3) & 4), the Applicant may apply for the special examination and approval only when submitting the production applications. **Priority review and approval procedure is issued on Feb.26,2016. Scope of priority review and approval** **1. Drug with significant clinical value satisfying following conditions:** **1).Innovative medicines not yet launched in domestic and overseas market** **2).Innovative new drugs with manufacturing site transferred to China** **3).Drugs with advanced formulation technologies, or innovative therapies, or sufficient clinical advantage** **4). Clinical trial application for drugs whose originator patent will be expired within 3 years; marketing application for drugs whose originator patent will be expired within 1 year.** **5). New drug CTA that applicant simultaneously filed the same application and got permitted to conduct clinical trial in EU or US; New drug NDA manufactured the product in China, which is undergoing simultaneous filing in EU or US and passed GMP/GCP inspection by EMA/FDA (products manufactured with same production line)** **6).Traditional Chinese Medicine with clear clinical therapeutic purpose in prevention and treatment for major diseases.** **7).New drug listed in the National Major Science and Technology Projects and National Key R&D Plan** **2.For below diseases prevention and treatment and can show significant clinical advantage** **1)AIDS; 2)TB;3)Hepatitis;4)Rare disease;5)Malignant tumor;6)Pediatric drug;7)Diseases with high incidence or unique in elderly people** **3.thers** **1). Post approval manufacturing process change of a generic drug with the aim to meet generic drug quality consistency compared with reference products** **2).For ANDAs which had been listed in CFDA GCP self-inspection Notice (CFDA notice No. 117 in 2015), if the applicant withdraw the application and then complete research to show quality and efficacy consistency compared with reference product, the later ANDA submission will be eligible for priority review.** **3).Urgent unmet medical needs and drugs in shortage. The List should be provided by NHFPC and Ministry of Industry and Information Technology. The list should also be reviewed by CDE and related agencies/ experts invited by CDE.** **The priority review and approval is applicable for both IND,CTA and NDA applications.The purpose of this document is to resolve the application backlog issue.**	usually no; except official request from Hospital Authority upon urgent situation	There is no formal priority review system. Depends on therapeutic area and unmet requirement.	There is no priority system. The review following the timeline of registration (100 or 150 or 300 working days)	The priority review system exists. Orphan drugs receive priority review automatically. New drugs not designated as orphan drugs which target other serious diseases and which are apparently expected to contribute to the improvement of quality of healthcare may be designated as "non-orphan priority review products" based on overall evaluation of the seriousness of the target disease and medical usefulness of the drugs. Designation is made based on the opinions of external experts if an application is submitted with an application for marketing approval.	The priority review system exists in **regulation but a specific guidance is under preparation.** 1) Drugs which target for life-threatening or serious diseases such as AIDS, cancers etc. 2) Drugs of which is deemed necessary because treatment is not possible with existing therapies due to resistance or other reasons 3) Other drugs such as anti-cancer agents, orphan drug, DNA chip etc : recognized by MFDS minister for patients or industrial development **4) Orphan drugs for unmet medical needs**	There is no formal priority review system in place. Priority review status will be provided on case to case basis, based on the applicant's justification. Timeline for Priority Review: 6-9 months	The priority review system exists. For serious diseases and life-threatening conditions and which are apparently expected to contribute to the improvement of quality of healthcare based on overall evaluation of the seriousness of the target disease and medical usefulness of the drugs. Consideration is made based on the opinions of external experts if an application is submitted with an application for marketing approval. Please refer to FDA Circular on Facilitation of Evaluation.	No separate priority review system or pathway. Only if product is submitted via Abridged Evaluation (with 1 reference country approval); and meets the pre-defined criteria in the guide (unmet medical need, etc). Grant of priority review is on case-by-case basis, at discretion of the Agency during Screening. Applicant will be notified at the point of acceptance of application, if request is granted.	The priority review system exists Unmet medical needs and drug for serious life threatening disease and is major medical advance can apply to priority review system. It should be apply for priority review first, after recognition by TFDA as priority review case then can be reviewed by priority review process. TFDA release new regulation for NCE -2 simple review regulation. For the product which launch in top 10 countries for over 10 yrs, the review process could be simpfy. For the product which approval by both USFDA and EMA and assessment reports provided, they product could also apply the simple reivew system.	There will be the fast track for life-threatening desease e.g. HIV drug, anti-cancer drug **by normal registration process or abridged registration**

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MDA Approval review	Orphan drug system	Presence of orphan drug system, Criteria for designation, Incentive, etc.	No orphan drug designation system.	No	The orphan drug system does not exists.	The orphan drug will evaluate will evaluated within 100 working days. No regulation establishing for Orphan drug.	The orphan drug system exists. Designation criteria Number of patients Less than 50,000 in Japan Medical need There are no appropriate alternative drugs or treatment methods. The efficacy and safety are expected to be outstandingly greater than those of existing drugs. Possibility of development There is a theoretical ground for using the drug for the target desease and the development plan is acceptable. Incentives (1) Subsidy payment(The total budget for financial year 2010 was 650 million yen.) (2) Guidance and consultation on research and development activities (HMLW, PMDA, NIBIO). PMDA provides a priority consultation system. (3) Preferential tax treatment (4) Priority review (5) Extension of re-examination period The re-examination period for the drugs will be extended up to 10 years.	The orphan drug system exists. Designation criteria -Prevalence is less than 20,000 in Korea -Drugs to treat diseases for which appropriate therapy and drugs have not been developed or have been significantly improved in terms of safety and/or efficacy, compared to existing alternative drugs - Products which do not meet the criteria above can be designated as an orphan drug if it is acknowledged that the limited supply of product would cause any serious harm to the concerned population or the MFDS minister recognizes it. Also there is a developed phase orphan drug in Korea.	Details given in DRGD 5.1.4 Registration Of Orphan Product. For all categories of products namely new chemical entities/new drugs, biologics and generics (including Non-Scheduled Poison product): i. Application for registration that being submitted to National Pharmaceutical Control Bureau (NPCB) will only be accepted/ considered after the products have been designated as orphan products. ii. Application for registration must be submitted via online system and with appropriate processing fee. iii. Upon receipt of complete application, the application will be processed within ninety (90) working days.	The orphan drug system does not exists but we have a DOH A.O. 4 s. 1992 for Compassionate Special Permit for life-saving drugs. This is the closest that we can get in as far guidelines for orphan drugs are concerned.	Available in Regulations but implemented as Named-Patient Basis pathway.	The orphan drug system exists. Designation criteria: Number of patients: the standard for rare diseases is if it's prevalent in less than 1/10,000. It is different with US (U.S. it is considered a rare disease if it affects less than 200,000 people/ prevalent in less than 7.5/10,000) and Japan (the number of patients total less than 50,000 /prevalent in less than 5/10,000) Definition of Rare Disease: The rare diseases specified in this Act refer to diseases with prevalence lower than that formulated and publicly announced by the central competent authority, and recognized by the Committee specified in Article 4 of this Act; or diseases designated and publicly announced by the central competent authority under special circumstances. Reward: 1. 10 years market exclusivity 2. To encourage the R&D and manufacturing of orphan drugs, TFDA announced and implemented the "Rewarding Standards for the Manufacturing and R&D of Orphan Drugs. But it focus on Domestic manufacturer. The rare disease drug which as a listed of new ingredient drug US FDA and EMA may apply NDA streamlined process (September 18, 2015).	Available, the requirement for orphan drug registration is only Admin part and some of Quality part.
	approval matters	You may append the approval matters with the attached paper.	・Approval number ・Marketing License Holder and its address ・Manufacturer and its address ・Non-proprietary Name ・Brand name in Chinese if applicable ・Active ingredents and Contents or Nature ・Dosage form ・Dosage strength ・Packaging size ・Shelf life ・Specification & test methods ・labeling and artwork ・packaging insert		・Generic Name ・Brand name ・Manufacturing Method ・Dosage and Administration ・Indications ・Storage Methods and Expiration Date ・Specifications and Test Method ・Name of the Manufacturing Site used to Manufacture the Product	Before Marketing Authorization , applicant receive Approvable Letter. In the Approvable Letter, it mentions some data to be submit (PI & packaging for commercial production, copy importation for import product only, if necessary NFADC will do on site inspection for local product before issued Marketing Authorization. The Duration between Approvable letter and Marketing Authorization Letter is two years. NAFDC will evaluate the data(with timeline 20 workdays) as requested before issued Marketing Authorization. The Marketing Holder will attached with Registration Form, Approved Package Insert, Approved Patient Information Leaflet. * Registration Form * Approved Labelling * Approved Package Insert * Approved Patient Information Leaflet	・Non-proprietary Name ・Brand name ・Ingredents and Contents or Nature ・Manufacturing Method ・Dosage and Administration ・Indications ・Storage Methods and Expiration Date ・Specifications and Test Method ・Name of the Manufacturing Site used to Manufacture the Product, Address, License/Accredetation Category, etc.	・Non-proprietary Name ・Brand name ・Ingredents and composition ・Appearance ・Manufacturing process ・Dosage and Administration ・Indications , Precautions for use ・Storage Conditions and Shelf-life ・Specifications and Test Methods ・Name and address of Manufacturing Site for DP and DS ・Proudct category: License/Accredetation, New Drug/ Orphan drug, etc., Therapeutic area, etc. ・Approval condition, if applicable.	Upon registration of a product by the Authority, the product registration holder shall be notified by the Authority and a product registration number (i.e. MAL number) shall be assigned to the registered product via the system.. Registration status of a product shall be valid for five (5) years or such period as specified in the Authority database (Re DRGD 8.5 Regulatory Outcome)			

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NDA Approval review	Other information concerning approval review			N/A		NCE should provide API Drug Master File or Internal Monograph as required in Part II Quality & GMP Certificate of API's manufacturer . Approval of SMF should also be considered to get approval of registration number.			As stipulated under the CDCR 1984, Regulation 11(1), the Authority may, at any time reject, as well as cancel or suspend the registration of any product if there are deficiencies in safety, quality or efficacy of the product or failure to comply with conditions of registration.			**TFDA issued the "Human cell therapy products application guidance" on July 13, 2015 and "Biosimilar drug of monoclonal antibody (Biosimilar mAb) NDA application guidance".**	
NDA Pre-approval inspection	GCP inspection		**CFDA has conducted the inspection of drug clinical trial data for all NDA/sNDA submitted for manufacturing or import. If not pass the CFDA inspection of drug clinical trial data, the product will not be approved for marketing by CFDA.**	Not required	DCGI may conduct GCP on-site inspection. DCGI will issue instructions to the CDSCO officers/Inspectors to conduct the inspection identifying the clinical trial site/ facilities to be inspected. CDSCO issued 'GUIDANCE ON CLINICAL TRIAL INSPECTION' in Nov. 2010.	GCP inspection for local clinical study in Indonesia. GCP inspection for import product is not required.	The GCP on-site inspection is executed by PMDA to 2 or 4 medical institutions and applicants.	GCP on-site inspection to sites, company and CROs according to MFDS's plan **(Pre-approval inspection for pivotal studies in Korea, Regular inspection).**	**The Guideline for GCP Inspection is intended to provide comprehensive information on National Pharmaceutical Control Bureau (NPCB) inspection programme and covers inspections at the clinical trial sites, clinical laboratories, computer systems, sponsors and/or contract research organisations (CRO), bioequivalence studies and independent ethics committee/ institutional review boards. This guideline is also intended to serve as a guide to the sponsors/CROs, local investigators and others on NPCB inspection procedures.** **Requirements as given in GUIDELINES FOR GOOD CLINICAL PRACTICE (GCP) INSPECTION**	The GCP on-site inspection is executed by FDA to medical institutions and applicants. Frequency not clear.	CT in SIngapore Pre-marketing approval application inspections are usually done announced and apply to completed clinical trials. Criteria during GCP Inspections: (i)Protocol (ii)Medicines (Clinical Trials) Regulations (iii)SG-GCP, adapted from ICH E6 on GCP (iv)SOPs for conducting clinical trials	The GCP on-site inspection is executed by TFDA around 4-6 weeks after CSR submitted to TFDA in selected medical institutions (depends on the number of involved site)	No requirement
	GMP inspection	ex. On-site inspection, Document inspection, CPP/GMP certificate from source country accepted	**GMP overseas inspections are conducted for some import drugs selected by CFDA during the CDE technical review of drug registration application or after IDL approval.**	Document inspection only, CPP/GMP certificate from source country accepted	GMP inspection of Indian mfg. units will be arranged before granting the manufacturing license and periodic review of the mfg. unit The Licensing authority or by any other persons to whom powers have been delegated in this behalf by the licensing authority of India may inspect the manufacturing premises of mfg. units outside India on need basis	For imported product : Based on evaluation of Site Master File, if necessary GMP inspection site will be request by NAFDC. **GMP Inspection Report from PIC/S country will be evaluate and can be consider for Waive on Inspection.**	Since the amendment of the Pharmaceutical Law (PAL) in April 2005, GMP compliance inspections have become a requirement that must be met for marketing approval. Application for GMP compliance inspections for all manufacturing sites listed in the applicaitions for marketing approval must be submitted to the GMP compliance inspection authority (PMDA or prefectures) by each manufacturing site.	GMP inspection can be done for manufacturing sites of drug product and drug substance. Basically MFDS conduct on-site inspection (from 2009). **For chemical products, some waiver period for on-site inspection would be allowed (5 years for non-sterile products, 3 year for sterile products). Even in case of on-site inspection waiver, GMP documents should be submitted.**	**On-site inspection required unless exempted.**	Since 1989, GMP compliance inspections have become a requirement that must be met for marketing approval. For foreign manufacturer, CPP and GMP certificate is being required.	GMP conformity assessment is required usually in document review. GMP certificates must be issued by PIC/S member, US FDA and/or Japan MHLW. If not, onsite inspection by HSA Audit Branch required, before product approval is granted.	**Foreign manufacturer has to be registered before NDA approval. The registration can be done by either PMF (paper review) or on-site inspection under PIC/S GMP standard. If multiple manufacturing sites are involved in different manufacturing process of the product (e.g., semi-product, bulk un-labeled, final packaging...), each of the sites has to be registered.**	GMP certificate (PIC/S) New foreign manufacturer may be inspected on site if needed.
	Other inspections	ex. GLP requirement and evaluation	**Since from Jul 22, 2015, all NDA applications should complete GCP inspection before completeing comprehensive evaluation in CDE before transitting to CFDA for final approval.**	Not required	N/A	In the GMP inspection site , the Laboratory is inspected by NAFDC . The Laboratory inspected following GLP requirements.	"Paper-based compliance inspections" is executed by PMDA to confirm whether data attached to NDA applications accurately reflect the results of clinical trials and other studies, and whether those are made in accordance with GCP, GLP and reliability standards.	Laboratory should get the GLP certification and GLP inspection will be conducted by MFDS	**NPCB also conducts other inspections including for GLP, GCP, GDP, BE centres.**	Paper-based compliance inspections is executed by FDA to confirm whether good distribution practice is being implemented.	Non-clinical studies providing toxicology information to support clinical trials should be conducted in compliance with GLP.	Current Taiwan had not perform GpvP inspection. But the regulation for GLP site inspection already exists and some study will be performed GLP site inspection. As to the regulation related to GpvP inspection is under discussion.	No requirement for GLP inspection

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Clinical trials	Necessary procedures to start clinical trials	The actual procedures to start clinical trials, for example, IND/CTA => import of investigational drugs => IRB etc.,	IND/CTA => import of investigational drugs and IRB (EC) review => Clinical Trial Management Committee review and approval of Office for Human Genetic Resource Administration (OHGRA) => start of clinical trial. clinical trial should be started within 3 years after obtaining CTA. (Additional approval process by clinical research management committee (CRMC) after IND approval was announced (国卫医发 (2014) No.80)) **Actually clinical trial management committee is not established in many clinical sites.** **Ministry of Technology and Science intends to raise the legal position of HGR regulation.** **All clinical trials with the involvement of foreign investement are required the submission and approval of HGR.**	a. IRB approval b. if study medication is required to be imported, then Application of clinical trial certificate (CTC) at Drug Office, Department of Health is required	Clinical trial on new drug shall be initiated after authorization by CDSCO and approval of respective EC. In case of parallel applications, CDCSO will grant conditional approval and note that the trial should start after Ethics approval. Trials should also be registered with CTRI (Indian Registry) before screening patients	After receiving Clinical Trial Approval Letter from NAFDC, the Clinical Study can be started.	Notice of claimed investigational new drug exemption to PMDA. Clinical trial can be started after 30 days if there is no comment from Authority	Get IND Approval and IRB approval in parallel. IND approval will be taken 30 days, however it will take about 2-3 months normally including additional data submission	Application to The Research Review Committee (RRC) & The Medical Research Ethics Committee (MREC) required. Also, application to the National Pharmaceutical Control Bureau (NPCB) for clinical trial import license (CTIL) is necessary. Parallel submission is possible. **(Re: Malaysian Guideline for Application of Clinical Trial Import Licence and Clinical Trial Exemption Edition 6.1)**	Clinical Trial Protocol approval is required. Please see FDA Circular 2012-007 (flowchart).	Approval by both HSA (to obtain CTC) and IRB approval are required respectively before start of clinical trial.	IND approval by TFDA＋Import permit of IMP → IND approval by IRB (IND in TFDA and IRB can be parellel) → CTA approval by medical insitiuation → Payment pay to medical institution completely →Site initiation visit. Since final ICF is approved by TFDA,it is needed to submit ICF appreved by IRB.(Notification:1011410615)	IRB/EC approval -> Investigational drugs import approval from Thai FDA -> initiation
	Necessary data/ documents/ brochures to start clinical trials	Necessary Tox data for initiation of clinical trials (specify local requirement other than ICH-M3 or S6)	Protocol & IB. Usually TOX data aren't required for initiation of clinical trial because all data have been reviewed by authorities. Because site/IRB always follows CTA.	Please refer to the guidelines (Guidance Notes on the Application for Certificate for Clinical Trial/Medicinal Test)	List of necessary Tox data is shown in APPENDIX III of Schedule Y, the Drug and Cosmetics Rules 1945.	Clinical Trial Documents consist of : UK-1 Form, Protocol, Investigator's Brochure, Informed Consent, Documents of trial drugs, Summary Protocol of Batch Production (for Vaccine and biological products).	Generally we will follow ICH requirement. Sometimes add reproductive toxicity testings before clinical trials.	**In May 2011, it was amended and inserted into the Enforcement Regulation of Pharmaceutical Affairs Act and, in March 2013, it was transferred to Regulation on Safety of Pharmaceutical Drugs Etc: Korean Good Clinical Practice (KGCP) of Medicinal Products, Specifications for Clinical Trial Control of Pharmaceutical Drugs**	Submission of Investigator Brochure is required.	Generally follow ASEAN requirement. Please see FDA Circular 2012-007	1. Clinical trial protocol 2. Patient information sheet and ICF form. 3. Subject recruitment procedures and advertisements (if applicable) 4. Listing of overseas trial centres (if applicable) 5. Principal investigator(s) CV 6. GMP certificate or certificate of accreditation 7. CoA (if appicable) 8. Letter of approval issued by IRB 9. Other relevant supporting documents, if applicable 10. IB	**Investigator brochure is required for clinical trial approval.**	ICH E6
		Are there any necessary documents/ brochures outside IND/CTA dossier	CRF & ICF Contract with site IRB approval Some sites require insurance certificate for the clinical trial **IMP Certificate Of Analysis(Some sites require GMP certificate), and PI's CV are requried.**	Please refer to the guidelines (Guidance Notes on the Application for Certificate for Clinical Trial/Medicinal Test)	As per Schedule Y Registration of clinical trial is mandatory in the ICMR Clinical Trial Registry prior to initiation of the trial.	Informed Consent to the patient	Documents needed to get patients' consent	CRF(Case Report Form), GMP warranty letter or certificate, documents to get patients' consent (in Korea)	Refer to CTIL guideline	Documents needed to get patients' consent. Please see FDA Circular 2012-007. Patient informed consent form is already part of the CTA dossier. Suggest answer should be: clinical trial agreements/contracts	Original declaration document of the principal investigator and sponsor has to be submitted	No extra document requires outside IND/CTA dossier. Only for biosample needs to send out to oversea, the statement from central lab is needed.	Material Transfer Agreement

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Clinical trials	Necessary data/ documents/ brochures to start clinical trials	Document Language (acceptability of English document)	In Chinese.	preferably English and patients consent form in English and Chinese/Chinese only	English **ICF: neccecary to translated into local language on site**	Indonesian or English	Usually Japanese documents are requested	Protocol and consent form should be translated into Korean. However English IB is acceptable to MFDS. Also phase I except FIH can be submitted in English	**Re: Malaysian Guideline for Application of CTIL & CTX Edition 6.1:- 4.6.2 Language: Application form must be filled in English or Bahasa Melayu. All data must be in English or Bahasa Melayu and must be legible. In cases where supportive documents is not originally in English or Bahasa Melayu, a copy of the document in its original language, accompanied by authenticated translation in English or Bahasa Melayu shall be submitted. The ICF has to be in English, Bahasa Malaysia, Mandarin and Tamil (where required).**	English For study documents to be used by healthcare professionals - English. For patient materials - English, plus any language applicable to the locale, eg Cebuano, Hiligaynon, HAS	English	**Both Chinese or English version are acceptable.**	Thai and/or English
	Requirement of domestic clinical data for NDA application, if there is foreign data	Necessary or Not-necessary -Necessity in PK / healthy sbj. -Necessity in patient data	Usually Chinese patient's data including DB study and PK study are needed, which indicates similarity in drug response (i.e. efficacy and safety) with foreign data.	Not necessary	Necessary waiver for clinical trial in Indian population for approval of new drugs, which have already approed outside India can be considered only in cases of national emergency, extreme urgency, and epidemic and for orphan drugs for rare diseases and drugs indicated for conditions/diseases for which there is no therapy (Office order dated 03.07.2014)	Generally, Indonesian patient's data requested which indicates similarity in drug response (i.e. Efficacy and safety) with foreign data for drug which used for family planning programme and other drugs based on request from Authorized body , for example public health programme for TB , etc.	Usually Japanese patient's data requested, which indicates similarity in drug response (i.e. efficacy and safety) with foreign data.	Foreign data is acceptable. But bridging data in Korean should be generated.	Not necessary	Local clinical trial is optional; PSUR submission will be required as part of Post-Marketing Surveillance. Comment: For NDA, there is no requirement in the Philippines,	Not necessary	**NCE has to submit Bridging Study Evaluation package before or simultaneously with NDA. If BSE successfully waived and at least 2 of 10R countries has approved (2 CPP), foreign data package can be accepted and no need to perform domestic study. If a bridging study is required, local PK or clinical data is required.**	Not-necessary
	Acceptance of foreign clinical data for NDA	Is there any conditional requirements, for example similarity in PK/PD?	No, just for reference. (Even if the similarity in PK/PD is indicated we can't rely only on foreign data to China NDA)	Yes (for NCE products) Not required for generic products	Foreign Clinical data can be a supportive document, however Indian data (PhaseIII) is must.	Acceptable if the clinical data following GCP and the result based on evaluation of safety and efficacy is good.	Acceptable if the similarity in PK/PD is indicated.	Acceptable; in case of similarity on S&E or PK/PD.	Yes	Acceptable if the similarity in PK/PD is indicated.	Yes	**NCE has to submit Bridging Study Evaluation package before or simultaneously with NDA. If BSE successfully waived and at least 2 of 10R countries has approved (2 CPP), foreign data package can be accepted and no need to perform domestic study. If a bridging study is required, local PK or clinical data is required.**	Yes
	Required number (or rate) of local subjects in pivotal clinical studies for NDA approval	Please explain for both local and multinational clinical trials, if necessary. *ex.* totally around 100 *ex.* 1/5 of all subjects in multi-national studies	At least 20-30 for Ph-1, 100 for Ph-2, 300 for Ph-3 in treatment group for local trial (for category 1 of chemical drug). For registration purpose, 100 pairs of Chinese patients in pivotal studies is requested whatever local studies or MRCT. Meanwhile, it is requested to show similarity in drug response and safety profile between Chinese and foreign patients in MRCT. Draft guidance on MRCT was issued for public comment in Nov 2014 and the tentative version has been publised by CFDA on Jan 30 and effective on Mar 1, 2015	Not specified	P-I: 1-2 centers. At least 2 patients. P-II: 3-4 centers. At least 10-12 patients **at each dose level.** P-III: a. The drug already approved/marketed in other countries: at least 100 patients distributed over 3-4 centres. b. The drug is a new drug substance discovered in India and not marketed in any other country: at least 500 patients distributed over 10-15 centres. (According to draft guideline **on Clinical trials and New Drug Approval 2011 - 2012**) However Now a days DCGI asks for 200 patients or more for Phase III studies for the drug approved/marketed in other countries depending on the prevalence of disease and therapeutics area. **(According to draft guideline on Biosimilars : Annex 11) There is a provision to consider 100 patients for Phase III and 200 patients for Phase IV trials or a combination of 300 patients for both Phase III + Phase IV trials combined.**	Local clinical trial is needed for new drugs for family planning programme, TB drugs, and others drug based on request from Authorized body.	It is requested to show the consistency in drug response between Japanese and foreign patients in multi-regional clinical trials. For this purpose, at least 15-20% of all subjects is hopefully to be Japanese.	No definite requirement. For both local and multinational clinical trials, statistically meaningful number of subject is needed.	N/A	There is no required number of local subjects in clinical trials for NDA approval. For PMS studies, it is suggested (but not required) that there should be 3,000 subjects. Comment: PhIV/PMS is still required but number of patients will be set by the type of the drug and the disease set by FDA (FDA Circular 2013-003)	N/A. But in the HSA CTC application, applicant has to declare expected number of subjects to be enrolled from each site.	it is request to show the consistency in drug response between Asia population and Caucasians in multi-national clinical trials. For this purpose, at least 15-20% of all subjects is hopefully to be Asian population. As for NDA approval, it was divided to two situation. Non-CPP: Early clinical development in Taiwan, Ph 1+ Ph 3 or Ph 2+ Ph 3.Taiwan patient No. for Ph1 study :≧10, for Ph 2 study: ≧20, for Ph3 study:≧80. One-CPP: One of Ph 1, Ph2 or Ph3 study in Taiwan. Taiwan patient No. for Ph1 study :≧10, for Ph 2 study: ≧20 or 10%, for Ph3 study:≧80 or 10%, or Multinational Ph3 study: total sample size ≧200 then Taiwan No.≧30 or 5%, total sample size ＜200 thenTaiwan No.≧10.	Not-necessary

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Clinical trials	Practicable number of clinical centers or sites in the country	# of sites with facility of clinical trials Is there any license system for clinical study site?	Involved clinical center or site should get a license of CFDA. More than 300 sites/hospitals are qualified by CFDA. **-Every qualified site need to be re-qualified every 3 years.**	Practicable no. of clinical study sites not specified; No license system for clinical study sites; however, the clinical study sites are usually university or government hospitals.	**More than 1000 sites**	It around 50 clinical centre .	Clinical trial can be initiated in many study sites. No license system for clinical study sites.	Certified sites by MFDS: **171** sites(**Nov. 2014**)	CRC (Clinical Research Centre) controls 30 clinical centers, 50 hospitals and 100 clinics.	Clinical trial can be initiated in many study sites. Protocols should be evaluated by IRB/EC. Comment: A clinical study site should have an ethics committee that is accredited or is ongoing accreditation procedures by PHREB.	There are 13 public hospitals and 16 private hospitals which can conduct clinical trials.	More than 100 hospitals can conduct clinical trials including 19 medical cenenters. (Delete "38 clinical sites get confirmation by TFDA for IRB certification and allow these 38 IRBs can do review and approve without TFDA approval. " since this announcement has expired. 78 Valid IRB name list is as "TFDA Certified IRB list" file 4. 78 of them have valid IRBs per TFDA inspection result. There is no license system for evaluate clinical study sites.	14 officially recognized sites (IRB/EC site) No (Beware of USFDA blacklist)
	IRB system for clinical trials	Installation of IRB/EC in sites Is there National IRB?	IEC at each site	Yes. An IRB for each cluster of hospitals	Independent Ethical Committee (IEC) & Institutional Ethics Committee **No National IRB**	There are National IRB system.	Institutional IRB.	There is not the national IRB but the Institutional IRB	Institutional and national IRB (MREC) available depending on sites. **There are 13 IRBs/IECs in Malaysia registered with the NPCB. These include the Ministry of Health Medical Research and Ethics Committee (MOH MREC), the Penang Ethics Committee and ethics committees from universities and private hospitals. Clinical trials conducted at these sites have to be approved by the respective IRB/IEC.**	Institutional IRB/Ethic Committee. The general guidelines on CT may be referenced from the "National ethical Guidelines for Health Research 2011 edition. Another reference is FDA Circular 2012-007 that recognize ERB/ERC for purposes of conducting CT of Investigational Medicinal Products and it also validates the agreement between the FDA and PNHRS or Philippine National Health Research System which includes the establishment of a clinical trial registry. Comment: Sites with its own EC should be accredited by PHREB or are currently undergoing accreditation process this year. For sites that do not have its own EC, the institutional ethics review board of UP-PGH can oversee and perform EC duties for that site.	Singapore has 2 clusters of public hospitals. 1 cluster is under NHG DSRB (National Healthcare Group Domain-Specific Review Board) and the other cluster is under SingHealth CIRB (Centralised Institutional Review Board). For private hospitals, they have their own IRB/EC	C-IRB is composed of 18 hospital IRBs. Some other sites may also take fast track for c-IRB approved trials. JIRB covers 85 hospitals. (this information is collected from C-IRB website) NRPB-IRB is composed of 20 hospital IRBs. Every medical center has its own IRB. There is different requirement between different IRB.	Available Yes, National IRB or Central IRB.
	Prevalence of GCP in clinical centers		GCP is observed in all clinical sites.	Yes	Yes. GCP is observed in all clinical sites.	GCP is observed in all clinical studies	GCP is observed in all clinical sites.	GCP is observed in all clinical sites. Same as Japan.	GCP is observed in all clinical studies. (Local recognized GCP certificate is compulsory for all investigators.)	Yes, GCP is observed in all clinical sites. ICH Guidelines, GCP E6 Comment: Mandatory for the Investigators and the site staff who are directly involved in the ccnduct of the clinical trial.	GCP is observed in all clinical studies	**GCP implementation in all clinical trials is mandatory since 1997.**	A must
	Investigators	ex. about 50 physicians have been trained in US/EC	Uncountable number of physicians in China.	Yes	Large pool of trained Investigators in diverse therapy areas	Investigator must have GCP training before the trial and understand the protocol comprehensively in order to conduct the trial in accordance to GCP. No requirement investigator have been trained in US/EC.	Uncountable number of physicians in Japan	Uncountable	**Current information not available.**	Uncountable number of physicians. In addition to CVs, IRBs require that investigators undergo GCP training and this should be renewed or refreshed every 2 years.	No info	TFDA regulated necessary training hours needed for GCP and ethical then qualified to conduct clinical trial. No actual number of investigator to get GCP training.	No information (Beware of USFDA blacklist)

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Clinical trials	Investigational drug	Condition of customs procedure	Tax and custom clearance. If imported investigational drugs to be used, CTA is necessary for Customs procedures and clearance.	Application of Import License based on the approved CTC	Permission to import of investigational product shall be obtained by applying for a test license. The application should be made in Form 12.	Sponsor request to import unregistered product was to NAFDC. Approval letter for Importation from NAFDC is used for release product in the customs. .		After the IND approval. Import permit should be gotten from Korea Pharmaceutical Traders Association in advance.	Clinical trial import license and proper clearance required.	Yes	Application for Import License of CTM required. Online application is possible. Can import less than the amount approved in the CTM, but not more. The approved CTM form needs to be submitted to the Trade Net office for custom clearance.	It needs to get import permit that issue from TFDA, then Customs will allow investigational product import into Taiwan within the quantity on the import permit.	Condition of customs procedure - import license, CoA, Air waybill, invoice, License Per Invoice
		Investigational drug labeling (requirements and language)	Chinese label is needed.	IP name; Strength, dosage, storage condition; manufacturer - English or English and Chinese	• "For Clinical Studies only" • Name or a code number of the study • Name and contact numbers of the investigator • Name of the institution • Subject's identification code	In Indonesia language for clinical trial in Indonesia.	Japanese label is needed	**1. "For clinical trial only" 2. The name of investigational drugs or identification marking (in case of blind design, both study drug and comparator should be indicated in the IP label), if necessary, formulation, administration route, quantity, assay of active ingredient or potency can be included in the label. 3. The lot number or code number 4. Name, address and telephone number of business/person who received the IND approval 5. The expiry period 6. The storage condition 7. "Keep out of reach of children" except when the product is for use in trials where the product is not taken home by subjects. 8. Reference code(clinical trial can be identified) 9. Subject identification number, treatment number, visit number**	Refer to CTIL guideline. English acceptable.	Yes, in English Comment: Import license is required for each shipment of Investigational Drug. The government body responsible for issuing this is the Phil FDA,	1. Designation or other identification mark on each item of such material. 2. Name/address of manufacturer. 3. Batch number. 4. Name or other identification mark of the subject. 5. Manufactured date and expiry date. 6. Storage condition. 7. 'The product should only be used under strict medical surveillance' 8. Must comply with GCP labeling requirements.	**Label has to be prepard in traditional Chinese under PIC/S GMP regulation.**	Require local language with product name or random number, dosage, amount, manufacturer, expiry date and the content of 'this product is used for clinical trial only'.
	Investigational drug	Usability of an unapproved drug as a comparator	No (almost impossible).	Yes	**Possible by applying for import license with the investigational drug**	Unapproved drug should provide data as below: Quality Data, Investigator's Brochure, and Summary Report of Non -Clinical & Clinical data, Summary of Batch Production Report (for Vaccines and Biological Product)	It is possible to use an unapproved drug as a comparator if the unapproved drug is the international standard drug. It is recommended to gather relevant safety information of the unapproved drug in Japanese.	Possible if the unapproved drug is the international standard drug. It is recommended to discuss with MFDS in advance.	Drugs approved in another country, but not in MYS, may be acceptable as far as appropriate supporting documents provided. Pls refer CTIL CTX Guideline Section 4.5.1 for Non-modified, registered out of Malaysia comparator product, and Section 4.5.2 for Modified comparator product.	It is possible to use an unapproved drug as a comparator if the unapproved drug is the international standard drug. It is recommended to gather relevant safety information of the unapproved drug.	As long as protocol and CTC approved, can be used	It is possible to use an unapproved drug as a comparator if the unapproved drug is the international standard drug. It is recommended to gather relevant safety and efficacy information of the unapproved drug in English.	Possible subject to IRB/EC approval

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Clinical trials	Export shipment of bio-samples from subjects	*ex.* possible, can be measured at Central Labs.	There is specific regulation for export of human samples. Samples can be exported after approval. **-CHGRAO(China Human Genetic Regulation Administration Office) released more strict regulation about sample in clinical study on Oct.2015.Please refer to 《人类遗传资源采集、收集、买卖、出口、出境审批行政许可事项服务指南》** **-Regulation of Human Genetic Resources Management (Draft submitted for Examination and Approval) is issued for public comments. It has a higher legal status comparing to "Interim Measures for the Administration of Human Genetic Resources" issued in 1998**	Possible	Possible	There are Regulation No.657 /MenKes/Per/VIII/2009 for export shipment of bio-samples from subject. The request for export of bio-samples to Ministry of Health.	Samples can be exported	Samples can be exported	Samples can be exported. Export permit required. Permission is valid for one year.	Possible, can be measured at central laboratory Comment: Exportation to central lab is permissible after being granted an Export Permit by the Bureau of Quarantine.	Can, as long as meet the importing countries necessary requirements. It is the applicant's responsibility to comply with importing country's requirements	Possible, can be measured at Central labs. But it needs statement from Central lab, also the information for the Central lab needs clarified in the statement in detail, ex address, contact window. If central lab is located in foreign, Sponsor/ central lab's warrent letter for export of sample (which is not dislinkage) is needed to obtain IRB and TFDA approval. according th TFDA annoucement regulation on Dec 28, 2011, (human research law). For Biogene sample, it needs to indicate the test gene information in advance then can allow to export.	Possible (MTA required by most IRB)
	Availability of multi-national CRO	*ex.* local branch, many local CROs	Multi-national CRO is available in China, such as Quintiles, ICON, Covance, ICN, PPD, PRA, RPS etc	Yes (domestic and multi-national companies)	Multi-national CROs like Quintiles, Parexel, PPD, ICON etc are available	Multi-national CRO is available in Indonesian.	Multi-national CRO is available in Japan	There are many multi-national CROs branch. Many local CROs.	Available	Multi-national CRO is available in Philippines	Available	Multi-national CRO is available in Taiwan	I am not sure
	Adverse reaction reporting during clinical trial	*ex.* SAE: report to Authority within 7 days etc.,	SAE: it is requested to report to the relevant authority in 24 hours after knowing the event.	Serious and unexpected adverse events - Fatal/life threatening: no later than 7 calendar days; submit report in 8 additional calendar days - Others: 15 calendar days NSAE and serious expected adverse events: - Brief summary at the end of trial	NewGazette GSR889(E) was published on 12 Dec. 2014. The rules of free medical management and financial compensation on 122DAB(30 Jan 2013) was ammended. Any report of serious adverse event of death occurring in clinical trial, after due analysis shall be forwarded by the Sponsor to Chairman of the Ethics Committee and Chairman of the Expert Committee constituted by the Licensing Authority as defined under rule 21(b) under Appendix XII with a copy of the report to the Licensing Athority and the head of the Institution where the trial has been conducted within **14 calendar days** of occurrence of the serious adverse event. While current provisions require payment of compensation in cases of injury or death of a subject occurring in a clinical trial due to the failure of an investigational product to provide the intended therapeutic effect, the notification changed this clause with adding supplementary item. It is effective from 12 Jun. 2015.	Investigator should report all serious unexpected adverse event to sponsor /CRO as soon as possible after known it, if there are some next adverse event, report a.s.a.p. until end of event. Sponsor should report all serious adverse event in Clinical Trial include death to Head of NAFDC and Ethics Committee within 15 days start from known the event , if there is next event, report it a.s.a.p until end of event.	Case of death by unknown adverse event have to be reported to PMDA within 7 days. Case of death by known adverse event and unknown serious adverse event have to be reported within 15 days.	**• Death or life-threatening SUSARs: within 7 days from the moment that the sponsor recognizes (the detail information should be additionally reported within 8 days from the first report)** **• Other SUSARs: within 15 days from the moment that the sponsor recognizes it**	Death or possibly leading to death SAEs within 7 days, other SAEs within 15 days in CIOMS-I Form. Pls refer to Malaysian Guideline for Safety Reporting of Investigational Products for more details.	SAE: report to Authority within 3-7 days. Please see FDA Circular 2012-007 (p.9-10) Comment: As per A.O. 2014-0034	Fatal or life-threatening unexpected ADRs: within 7 calendar days. All other serious unexpected ADRs: within 15 calendar days. (See Guidance for Industry: Safety Reporting Requirments for Clinical Drug Trials)	SUSAR: report to Authority within 7 days for death and life threatening case, within 15 days for other cause. It is same as international rule.	To FDA: Only Local SUSAR , death or life-threatening related to study product within 7 days, other local SUSAR within 15 days (from sponsor awareness) To site IRB/EC: Death or life-threatening within 7 days , other SAE within 15 days (FERCIT)
	GCP site inspection		There are 30-50 cases per year of Triggered Inspection conducted by CFDA or PFDA which are triggered by complaints/requests from CDE/CFDA. Annual inspection plan-based Routine Inspection conducted by PFDA is also available. **-CFDA and PFDA conducted large-scale inspection to unwithdrawal study that submitted for NDA approval on sites from end of August 2015.(For improving the clinical study quality in China)**	Accreditated to the sites by separate parties	Yes.		After NDA, PMDA inspects the applicant and 2-4 medical institutions based on GCP.	Yes	Yes		Will be conducted by the HSA Clinical Trial Branch, on locally conducted clinical trials.	TFDA is planning to conduct overseas GCP inspection for CSRs submitted for Taiwan NDA registration. Details pending discussion between authority and industry.	Yes

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Manu -facturing	Acceptance test for Import drug	How the specifications & test methods for acceptance test of import drugs are set in your country?	**QC test for 3 batches should be conducted by NIFDC. Specification and test methods should be approved by CFDA at the stage of NDA.**	Based on the approved particulars.	Specifications and test methods are to be set according to registered specifications. Official in pharmacopoeia or in-house specifications with validation data are available.	Specification and test methods are following Indonesian Pharmacopoeia, USP/NF, BP, EP, JP.	Specifications and test methods are to be set according to JP.	Specification and test methods are usually set in accordance with official compendium or registered in-house specifications.	**Both compendial and non-compendial specifications are accepted.**	Specifications and test methods are to be set according to registered specifications.	To be tested according to approved specifications & test methods	Specification and test methods are to be set according to international pharmacopoeia, like JP, EP, USP/NF. For innovative product, it is allow to use Company Own specification and test methods with validation data and scientific justification.	Both compendial and non-compendial method are acceptable
	Pharmacopeia	What is standard pharmacopeia ? What is other accepted pharmacopeia? ex. USP/NF, JP, EP	**All import drugs and domestic drugs should follow Ch.P2015.**	BP, USP, EP and JP. In-house specification for NCE would be accepted by DOH.	If a DP/DS is official in the Indian Pharmacopoeia(IP) than must conform to IP if not official in IP than BP/USP/EU Pharmacopoeia standards are to be followed	Standard Pharmacopoeia : Indonesian Pharmacopeia Other accepted Pharmacopoeia : USP/NF, BP, EP, JP	JP (Japanese Pharmacopeia)	Standard : KP Accepted : JP, Ph. Eur(EP), USP(NF), BP, Deutshces Arzneibuch, Pharmaacipee Francaise	The main pharmacopieal references are BP and USP. Others are JP and EP.	JP, USP/NF, EP, BP, PP (Philippine Pharmacopoeia)	**Pharmacopoeias accepted by HSA are Ph. Eur., USP, BP, and JP**	Accepted pharmacopoeia are JP, EP, USP/NF.	USP 34, NF 29 and supplements, BP 2011 volume 1-5 and Addenda, the fourth edition of IP and supplements, Thai-pharmacopoeia II volume I part 1 and supplements, the seventh edition of EP and supplements
	GMP system	What is current GMP requirements? ex. PIC/S	Chinese GMP 2010 version(MOH order 79)	PIC/S has been adopted for local manufacturer licensing PIC/S would be adopted for overseas manufacturer within a few years.	Indian GMP as outlined in Schedule M of DRUGS AND COSMETICS RULES, 1945 Then, these regulations and guidelines (Schedule M) were revised in order to be based on WHO-GMP in 2003.	PIC/S GMP requirements	**Japan has been a member of PIC/S GMP since July in 2014.**	**As South Korea joined to PIC/S membership in July, 2014, MFDS has been prepared a provision to harmonise the Korea Good Manufacturing Practice (KGMP) of Pharmaceutical Drugs with PIC/s guidelines and issued, MFDS Notification No. 2015-35 in June, 2015. The validation of GMP certificate is for 3 years from the completion of GMP inspection.**	The current PIC/S Guide to GMP for Medicinal Products and its Annexes have been adopted as the standard used by NPCB to assess the GMP conformity of manufacturers.	Philippine applied for membership in the PICS (June 2009) --> PFDA has offically adopted the PICs Guidelines for GMP of medicinal products as per AO 2012-0008	PIC/S GMP requirements	Taiwan is PIC/S member since Jan 2013. Both the imported drug substance used in the domestic manufactured drug product and the drug substance used in the imported drug product should satisfy requirements for PIC/S GMP since Jan. 1st, 2016. However, TFDA has not shown the exact process of the application for the GMP compliance assessment yet. **TFDA issued the "Good Manufacturing Practice of Active Pharmacuetical Ingredients (API) for Preparation Using" on July 31, 2015. TFDA requires applicant to submit the GMP Certificate for API.**	**Applied for PIC/S membership 2015 March 20).**

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Manu -facturing	GMP system	Please describe GMP evaluation process by the authorities. ex. GMP clearance/ accreditation required before NDA ex. On-site or document inspection ex. Acceptability of GMP certificate from original country	1)For local drugs, GMP compliance is pre-requisite to obtain a Product Marketing Approval in China (see "NDA" - GMP inspection). GMP inspection to licensed manufacturer is carried out every five years by on-site inspection. An application for GMP renewal should be submitted 6 months before GMP expiration. 2)For import drugs, GMP on-site inspection started recently. Some selected drugs were inspected at foreign site after license approval.	For overseas manufacturer, inspection is usually not required. For local manufacturer, an inspection by pharmacist inspector will be conducted at the company's premises within 2 weeks from the submission of a new application. The application will be considered by the committee. If approved, a license valid for 1 year will be granted.	GMP inspection will be arranged before granting the manufacturing license and periodically The Licensing authority or by any other persons to whom powers have been delegated in this behalf by the licensing authority of India may inspect the manufacturing premises of mfg units outside India on need basis.	The manufacturer which is first time register export product to Indonesia should provide SITE MASTER FILE (SMF) for GMP evaluation. After evaluation of SMF, the NADFC will approve to continue registration process of NDA or request site inspection. Before inspection, the manufacturer should provide Pre-inspection document for preparation of the site inspection . After inspection, the NADFC will issue approved or reject to continue registration NDA. **The inspection report from other Authorized Health Authority can be consider for Waive of Inspection to the Manufacturer .**	GMP compliance is pre-requisite for obtaining a Product Marketing Approval in Japan (see Pre-approval inspection, GMP). GMP inspection to licensed manufacturer is carried out every five years either by on-site or document inspection.	Pre-approval GMP review: 1) documents (Minimum requirements) -based 2) Site inspection. In case MFDS visits the same site within 3 years for another products which used the same manufacturing method, on-site inspection could be waived. (In case of biologics, exemption period is maximum 2 years.) Even though MFDS does not visit the site, documents for GMP review should be submitted. 3) Supplementary request after site inspection	**NPCB is a PIC/S member and follows the PIC/S Guide to Good Manufacturing Practice for Medicinal Products. PRH must provide acceptable evidence to show that the manufacturer of the product follows an internationally accepted standard of Good Manufacturing Practice (GMP) and recognized by the Authority in Malaysia.**	GMP compliance (or better yet GMP Clearance) is a pre-requisite for the site registration of the manufacturing site and source into the License to Operate, which then is a requirement in obtaining a Product Marketing Approval in Philippines. Current evaluation for foreign sites is based on documentation review but the FDA may require on-site inspection depending on results of documentation review. GMP inspection of licensed local manufacturer is conducted by local FDA every 2 years, GMP recognition system of overseas manufacturing sites was introduced as per AO 2013-0022.	Domestic manufacturers in Singapore are subjected to licensing and periodic GMP audits by HSA. All new overseas manufacturers will be subjected to a GMP Conformity Assessment by HSA. Refer to Guidance Notes on GMP Conformity Assessment of an Overseas Manufacturer (Dec, 2008)	GMP compliance on-site inspection is pre-requisite for NDA approval for new manufacturing site. The already registered manufacturing site should be get routine GMP renewal (follow up management) through onsite inspection or document inspection every 2 to 4 years depends on the first approved expiry date.	**No longer allow submission of GMP accreditation in parallel.**
		Please describe frequency/number of on-site inspections to domestic/overseas manufacturers by the authorities. ex. number of inspections conducted in last year	**The overseas manufactures for 34 products of some foreign companies were inspected by CFDI in 2015. 28 products were inspested in 2014. (http://www.cfdi.org.cn/ccdweb/view?oid=menunews&ntyp=D01)** **The list of products to be conducted overseas GMP on-site inspections by CFDA in 2016 is issued and includes 49 import drugs. (http://www.cfdi.org.cn/ccdweb/main?fid=open&fun=show_news&nid=7210)**	Since the manufacture license valids for only 1 year, inspection will be made at least on annual basis for local manufacturers	Annually. For overseas, CDSCO started inspection of Pharmaceutical firms for import registration of drugs. Six on-site inspections in 2011 for DS manufacturing site in China, and four China drug manufacturing sites in 2012.	Every month there are on site inspection to domestic and overseas manufacturers by the Authorities. Almost Asia countries are inspected.	Number of on-site GMP inspection to overseas manufacturer in FY **2014** was **74.** About **70%** are in Asia. On-site inspection to Japanese domestic manufacturer by PMDA in FY 2012 was 132.	Number of on-site inspection to overseas manufacturers in 2011 was 90. Domestic manufactures in 2011 : 232 by MFDS (90 by other authorities, e.g. FDA, EMA)	**The number of GMP Inspections conducted in 2014 was 360. Of these, the number of inspections on pharmaceutical premises was 68.**	No details as of this moment. For overseas manufacturing sites, please note that FDA Phils may require conduct of on-site inspection where GMP certificate submitted was issued by a non-PICs member Regulatory Authority.		**Overseas inspection in 2015: 33. No data for domestic inspection yet.**	- Domestic: Non-sterile drug: every 3 years Sterile drug: every 1.5 year - Overseas: if needed FDA's plan on inspection: (Note: The FDA is working on the update of this regulation, but not come out yet at time of report) • Routine Inspections ~ 60-70 plants/year • Special inspection in special case • And there will be Follow up Inspection which they are setting on criteria (may be from Risk Assessment).

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			RDPAC	HKAPI	OPPI	IPMG	JPMA	KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA
Manu -facturing	DMF system	Please describe DMF system (or plan for introduction). Is DMF mandatory or optional?	DMF system is investigated but not yet implemented.	Not specified	No DMF system exists. (Note: CMC part of application dossier is called DMF, but it does not mean DMF system as in other countries.) API DMF as per ICH CTD is also acceptable.	DMF **(open & closed part)** of API are needed as mandatory for generic and NCE API .	The submission of MF (Master File) is optional. Drug substance, Intermediate, New excipients, Packaging materials etc. are subjects of MF.	NCE and API for generics should be submitted DMF since 2002. But all APIs should be registered by 2015. (Every year, MFDS announced the list of APIs which should be registered.) Only drug substance(API) is subject of DMF.	A DMF is required for API registration, and may be replaced by a CEP or full details of Part II S ACTD. API registration is being implemented in phases.	With the adoption of the ASEAN CTD, maintenance of DMF is mandatory based on requirements stipulated on the ASEAN Variations Guideline.	Yes. It is optional to use DMF in application submission. DMF Submission FORM in Appendix 18(effective 1April 2014. See UPDATE Jan 2014: Guideline on Medical Ptroduct Registration in Singapore)	Current only DMF regulation for drug substance available. But now it is no mandatory request for all API. TFDA will announce the product list for DMF compliance in next year. It may effective since year 2016 for all API. The 1st stage DMF management regualtion is announce on May 21, 2013.	No DMF system
		Annual or periodical update reporting required?	DMF system is not implemented yet.	Not specified	N/A	N/A	No annual updated system. Partial change application or notification is required for changes.	Annual report should be submitted by Jan. 31 every year if the relevant changes are applicable for the subject of annual report	**DMF is one of the 3 options for Regulatory Control of APIs. Assessment of APIs data and information include changes and variations submitted by the product registration holder (PRH)/API Manufacturer. Assessment of an API will also be performed for a registered product prior to a product renewal application, which is required every 5 years presently.**	N/A As applicable	Applicants are responsible to maintain and update the DMF. When a DMF has been updated, the DMF Submission Form and a summary table of changes made in the DMF update must accompany the updated sections of the DMF. If there are changes to the DMF that will result in a post-approval variation to the drug product, applicants must file a post-approval variation	No annual updated system. Partial change application or notification is required for changes.	Not required
	Contents of packaging label and language	Please describe required contents of packaging label and language to be used. ex. refer to guidance document	The required contents are described in CFDA order 24. The contents should be written in Chinese.	English or English and Chinese, requirements decribed in Guidelines on the Labelling of Pharmaceutical Products	The required contents are described in rule 96 & Schedule D2 of the Drug and Cosmetic Rules 1945. PI and packaging labels should be written in English.	New guideline 2011 for labeling prescription drug : request to provide Package insert (English or Indonesia), Patient Information Leaflet (Indonesian), outerbox should following packaging requirement (name of the product, active substance, volume, indication, contraindication, dosage and administration, storage condition, manufacturing name & address , imported by,) also retail price, Registration number, Harus dengan resep dokter, Logo of prescription drug. In the label, after product name should follow active substance names, Label also following regulation on registration. Guideline for OTC : inner box and all product information should be in Indonesian language.	The required contents are described in Article 50 of the Pharmaceutical Affairs Act. The contents Should be written in Japanese.	**For pharmaceutical products including prescription only, OTC drugs and quasi-drugs, the labelling is the summarized indication of efficacy and safety that must be exactly same to the registered/approved product information by the Korean Health Authority. This is presented through three types of labelling like the following: · Package leaflet · Container · Carton (outer package) The required information including product name, lot number, dosage form, name and address of manufacturer or importer, etc. is defined in Articles 56, 57, 58, 59, 60 and 65 of the PAA and Articles 69, 70, 71, 74, 75, 76 and 77 of the Regulation on Safety of Pharmaceutical Drugs etc.**	The labeling content is stated in Drug Regulatory Guidance Document. The labeling for pharmaceutical products are in English or Bahasa Malaysia. Some labelling statements are mandatory in Bahasa Malaysia, eg for “Keep medicine out of reach of children”.	The required contents are described in Generic Labeling Law. The contents Should be written in English. (see A.O. 55, series 1988)	Refer to: GUIDANCE ON MEDICINAL PRODUCT REGISTRATION IN SINGAPORE APPENDIX 6 POINTS TO CONSIDER FOR SINGAPORE LABELLING. The product labels, PI and/or PIL must be in English. If non-English text is included in the labelling, applicants must provide an official statement to declare that the non-English text is complete, accurate and unbiased information and is consistent with the English text.	The required contents are described in Article 20 of "drug review and registration guideline". The contents **of outer box** should be in English and Chinese. **Chinese packaging insert is mandatory while English PI is optional.**	Follow ASEAN labeling requirements Thai language required for - category of drug - expiration date - special warning **package leaflet in Thai.**

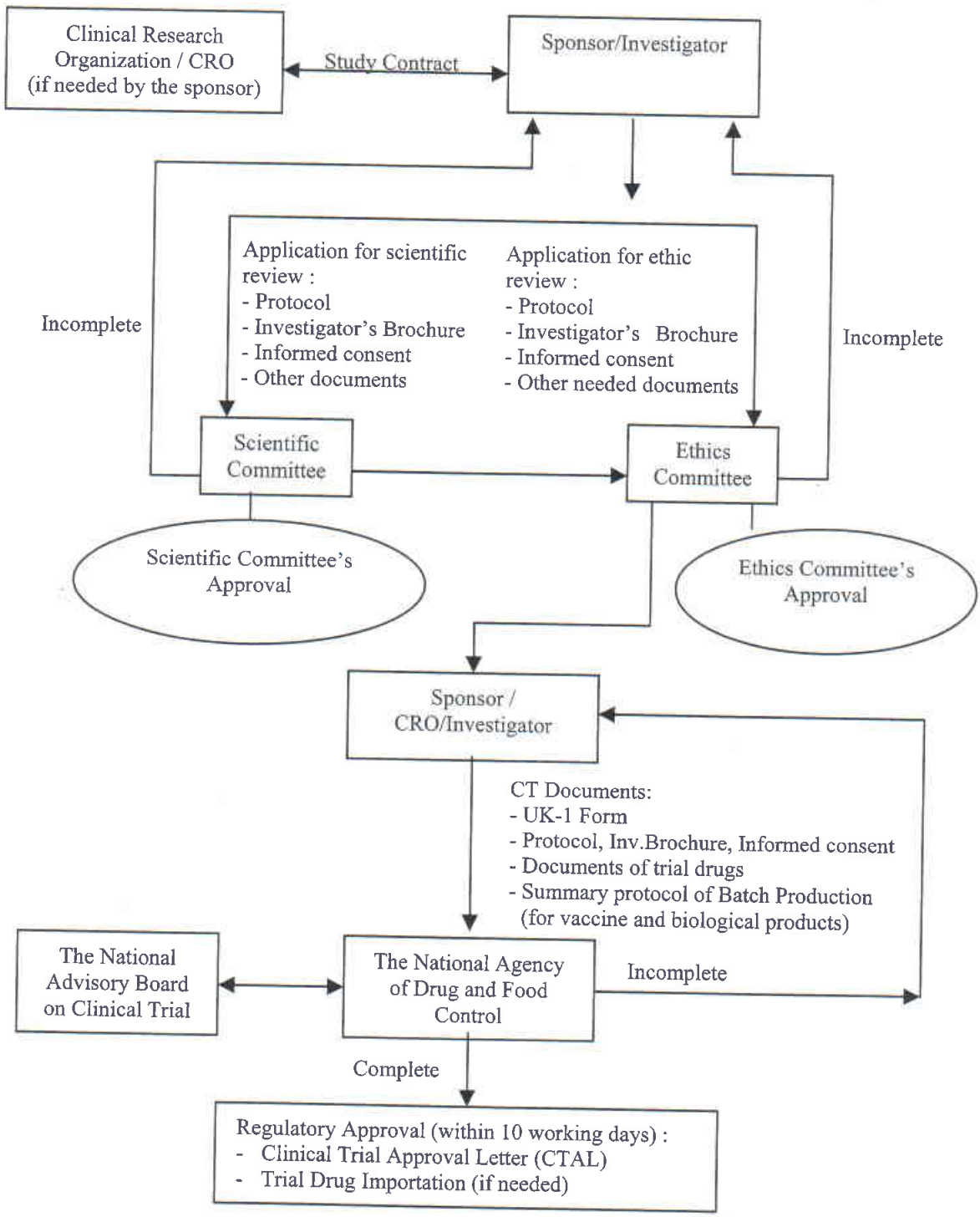
Item	Contents	Detail or Example	China RDPAC	Hong Kong HKAPI	India OPPI	Indonesia IPMG	Japan JPMA	Korea KRPIA	Malaysia PhAMA	Philippines PHAP	Singapore SAPI	Taiwan IRPMA	Thailand PReMA
Manu -facturing	Bar code on packaging materials	Please describe requirements of Bar Code on packaging materials and concerned regulations.	Bar code on packaging material for national essential drugs should be completed by Feb. 2012, while the deadline for whole drugs is Dec. 2015. **CFDA announce that drug electronic supervision code suspends temporarily on Feb.20,2016.**	For product registration, no concern. For supply to government hospital: GTIN barcode as issued by GS-1	For product registration, no concern. For supply to government hospital: GTIN barcode is required Barcode requirements using GS1 identification standards has been implemented. (reference: The Office Memorandum No: Z-16025/02/08-EPW dated 6th May 2011 by MoHFW). For local Indian market, it is still not made mandatory.	No regulatory requirement on bar code. It is an internal company logistics requirement.	The contents Should be written in Japanese.	**MOHW Notification No. 2013-63 was issued to build the base of distributional information of domestically manufactured or imported pharmaceuticals by determining identification with barcodes/RFID tag. Except several products, all pharmaceutical drugs including the imported products must adhere a barcode since 2009. There are three codes of GS1 system, which can be used on the barcode.**	Bar code is an optional information.	Barcode is required per SKU. It is a requirement upon submission of new drug applications with effective date on June 2015.	No regulatory requirement on bar code. It is a internal company logistics requirement.	Current barcode labeling of product code is required to carry product name in Chinese and English, generic name, dosage form, strength, and MA holder depending on package unit (carton) or outer box. Barcode regulation on product unit (per tablet for blister, per bottle, per vial for injection) is draft and under discussion. The requirement for the barcode will be GTIN(GS1) data matrix.	No regulatory requirement for Bar code But some hospitals require barcode.
Post approval	Renewal system of approved license	Please describe renewal system of marketing authorization or manufacturing license. ex. renewal required every 5 years ex. re-evaluation system	Manufacturing license system is adopted for registration management. So, renewal system is based on manufacturing license. Renewal is required every 5 years, and should be submitted within 6 months before expiration date of license.	Renewal required every 5 year.	Renewal system has been implemented for the followings. 1) Import license (Every 3 years. Renewal application should be made three months before the expiry of the existing license.) 2) Registration certificate (Every 3 years. Renewal application should be made nine months before the expiry of the existing license.) 3) Manufacturing license (Every 5 years. The license will be expired if the renewal applications not made within six months of its expiry) Marketing Authorization is one time issue, no renewal required.	Marketing Authorization: Renewal application is required every 5 years. Renewal application needs to be submitted by 120 days-prior to license expiry. If needed, the NADFC conducts re-evaluation. Renewal of Import Product should attach new CPP (Certificate of Pharmaceutical Product). Manufacturing License: Renewal application is required every 5 years for-every GMP facility and dosage form. Sometimes the NADFC will inspect the GMP facility before granting the renewal of Manufacturing license.	Not renewal but re-examination system is adopted. Drug monitoring is required for 8 years for NCE drug, 4-6 years for new indication/ administration route and 10 years for orphan drug.	Renewal system of approved licenses will be implemented from drugs which would be approved in 2013 (applicable for existing drugs as of Jan. 1, 2018). Documents should be submitted : 1) Summary reports on Safety and Efficacy of the drug product including the last 5-year 2) Usage in foreign countries, Any action related to safety in foreign countries 3) Data on Product Quality 4) Safety update report 5) In case anything would be changed from approval, its evidential data 6) Document on Drug Display (Label in carton, PI and so on) 7) Manufacturing or Importing records during the last five-year 8) Product Permission letter issued by MFDS	Renewal is required every 5 years of a product registration. Renewal needs to be submitted 6 months prior to registration expiry.	Renewal system is being implemented. Renewal for products under Monitored Release status is after 3-5 years. Products on regular registration status, i.e. under Initial or Renewal status, renewal is done every 5 years. .	Product licenses should be renewed every 12 months. If the MAA holder doesn't complete to submit the renewal application by 45th days before the renewal deadline, HSA inform MAA holder of the status. Auto renewal system is implemented since 2009. HSA require the CPP for renewal submission for MAA, and the CPP should be within 6 months since the CPP is issued.	Renewal system of approved license is existed. The approved license needs to be renewed every 5 years.	There are 3 kinds of license in Thailand which are Manufacturing license, Import license and Sale license, all of which require annual renewal. Based on current Thai Drug Act, the product license is life-long, no requirement of renewal, except for drug classified as narcotics and psychotropics shall subject to renewal every 5 years. **Product license will be automatically withdrawn if no production/importation every 2 consecutive years.**

Item	Contents	Detail or Example	China RDPAC	Hong Kong HKAPI	India OPPI	Indonesia IPMG	Japan JPMA	Korea KRPIA	Malaysia PhAMA	Philippines PHAP	Singapore SAPI	Taiwan IRPMA	Thailand PReMA
Post approval	Post marketing surveillance or safety monitoring program	PSUR submission required? Other post-approval safety requirements ? ex. Safety monitoring program/monitored release	Annual PSUR submission is mandatory until the first renewal date, and it becomes every 5 years after the first renewal date. Mandatory special monitoring is performed over drugs within the new drug observation period as well as drugs imported for the first time within 5 years. The monitoring results shall be summarized, analyzed, evaluated and reported as required.	For NCE only. PSUR has to be submitted every 6-monthly for the first 2 years of product registration approval, and annually in the following 3 years.	PSUR submission is mandatory for a period of four years. For new drug, every 6 months for the first 2 years, and annually for another 2 years. May be extended by the authority in the interest of public health. (Reference: Schedule Y of the Drugs and Cosmetics Rules amended in 2005) PSURs due for a period must be submitted within 30 calendar days of the last day of the reporting period. For conditional approval, there is a case where Phase IV crinical trial imposed.	PSUR submission is required only for NCE and certain product if it is required by HA. There is an obligation to report all Adverse Events (unexpected/expected , serious/ non serious in Indonesia or foreign countries) to NADFC .	PSUR submission is mandatory every 6 month in first two years and annually after two years. Use-result survey data should be submitted together.	PSUR submission is mandatory every 6 month in first two years and annually after two years. Use-result survey data should be submitted together.	PSUR/**BPRER** is mandatory for NME: 6 months once in the first 2 years, and 12 months once in the subsequent 3 years.	As per PFDA Circular 2013-004, the post marketing surveillance system was enhanced to cover all registered products. Periodic (minimum on annual basis) submission of PSUR/ PBRER, and AE reports and submission of RMP ~~is~~are required.	**The preparation of PBRERs for regulatory authorities is a routine pharmacovigilance activity outlined in the ICH E2E guidelines. The guidance on the format and content of the PBRER can be referenced from the latest version of ICH E2C(R2): Periodic Benefit-Risk Evaluation Report, available at (http://www.ich.org.)** **Details can be found at (http://www.hsa.gov.sg/content/dam/HSA/HPRG/Safety_Alerts_Product_Recalls_Enforcement/Guidance for Industry_Post-marketing Vigilance Req for Med Prod_June 2015.pdf)**	PSUR submission is mandatory every 6 months in first two years and annually after two years. For NCE product, it necessary to submit PSUR in first 5 years. Other post approval safety requirement like RMP/REMs will be initiated by TFDA or Pharmaceutical company, it depends. For non-CPP NDA submission case, it is mandatory requirement to submit RMP/REMs together with NDA submission. For one-CPP NDA submission case, it may request by TFDA after their evaluation. **GPVP (Good Pharmacovigilance Practice) was implemented since 2008.**	Yes, T-FDA requires PSUR for unconditional approval of New drug. SMP (Safety Monitoring Program) for NCE is required under conditional approval for 2 years.
	Risk Management Plan (RMP)	Please describe requirements of RMP/REMS. ex. Mandatory at NDA, submit up on request from the authorities	Not yet officially implemented. For the product which is accepted for special review procedure, Risk Management and Implementation Plan should be submitted at NDA.	One of the mandatory requirements for NCE registration	N/A at present	Not required yet. RMP regulation will establish later on. RMP is necessary for the application of category 1. (Article33, No.HK.03.1.23.10.11.08481)	RMP document is mandated for NDA as M1.11.	**For improved management and control for known or potential risk of post-approved drug product, a risk management plan (RMP) was introduced from 01-Jul-2015.** **For approval of new drugs and orphan drugs, the Risk Management Plan (RMP) should be submitted with application form in accordance with amendment made by MFDS Notification No. 2015-27.** **The scope of drugs required to submit the risk management plan will be expanded annually step by step by 2018.**	RMP is listed as a requirement in the DRGD for biological products, including biotech products, biosimilars, vaccines and blood products.	RMP is requirted for submission of NDAs (FC-2013 004). There's no local format of RMP.	**The submission of RMP documents in support of all NDA-1 and biosimilar applications is mandatory. For other product application types, such as NDA-2/3, MAV or GDA, HSA may also request for the submission of RMP documents on a case-by-case basis following the evaluation of the application dossier.** **Details can found at (http://www.hsa.gov.sg/content/dam/HSA/HPRG/Safety_Alerts_Product_Recalls_Enforcement/Guidance for Industry_Post-marketing Vigilance Req for Med Prod_June 2015.pdf)**	Mandatory at NDA for non-CPP product. **TFDA may also request RMP for products considered as necessary, during reviewing period or post-marketing stage.**	Require for some specific group. Ex. Thalidomide .

Item	Contents	Detail or Example	China RDPAC	Hong Kong HKAPI	India OPPI	Indonesia IPMG	Japan JPMA	Korea KRPIA	Malaysia PhAMA	Philippines PHAP	Singapore SAPI	Taiwan IRPMA	Thailand PReMA
Post approval	Adverse drug reaction reporting after marketing	Please describe reporting requirements of ADR for marketed products.	Reporting is mandatory for ADR observed in post-marketing period including PMS. Reporting period of Serious ADR and unknown ADR are within 15 days (30 days for non-Serious ADR for drugs within the new drug observation period or imported drugs within 5 years from the date of initial import permission).	For generic products, reporting is by means of voluntary basis. For NCE, SUSARs have to be reported within 15 calendar days from date of first receipt.	Serious unexpected adverse reactions: must be reported to the licensing authority within 15 calendar days of initial receipt of the information by the applicant. Other: to be reported in PSUR.	Reporting is mandated for ADR observed in post-marketing products. 1. AE Spontaneous serious unexpected in Indonesia , as soon as possible, not more than 15 calendar days. 2. AE spontaneous non-serious unexpected in Indonesia, report every 6 months. 3. AE Spontaneous serious expected in Indonesia, as soon as possible, not more than 15 calendar days. 4. AE spontaneous serious unexpected in froiegn countries, as soon as possible, not more than 15 calendar days.	Reporting is mandated for ADR observed in post-marketing products including PMS. Reporting period of Serious ADR is within 15 days (or 30 days for expected ADR).	Reporting is mandated for ADR observed in post-marketing products including PMS. SAE : within 15 days from reported day NSAE : within next year Feb from reported day	Reporting is mandated for ADR observed in post-marketing products including PMS. Non serious ADR / Serious but non-life threatening ADR: 15 days from date learned; Serious ADR(fatal and life threatening is within 7days.	Reporting is mandated for ADR observed in post-marketing products including PMS. Reporting period of Serious ADR/AE, ICSR is within 5 days and serious one must be reported promptly.	Fatal/life-threatening ARs: NLT 7 calendar days. (If MAA holder can not complete the report by the first report, they should submit the completed report within NLT 8 calender days. Serious ARs: NLT 15 calendar days. Product withdrawal/product recall/product defect: Within 24 hrs Significant safety issues: Within 7 calendar days **See GUIDANCE FOR INDUSTRY POST-MARKETING VIGILANCE REQUIREMENTS FOR MEDICINAL PRODUCTS, June 2015 (http://www.hsa.gov.sg/content/dam/HSA/HPRG/Safety_Alerts_Product_Recalls_Enforcement/Guidance for Industry_Post-marketing Vigilance Req for Med Prod_June 2015.pdf)**	Reporting is mandated for ADR observed in post-marketing products including PMS. Reporting period of Serious ADR is within 7 days for death and life threatening, within 15 days for other Serious ADR.	Follow Guidance for Industry Post-marketing Safety Reporting Requirements for Human Drug and Biological Products Including Vaccines (Annex 10)
	Variation guideline	Is there any guideline document for post-approval changes? If yes please show the title.	The variations to be approved or filed are listed in Drug Registration Regulation order 28. Meanwhile, Guideline for Variations of Post-market Chemical Drug Products has been implemented.	Please refer to the guidelines for Change of particulars (Guidance Notes on Change of Registered Particulars of a Registered Pharmaceutical Product **; issued by Drug Office, Department of Health of Hong Kong).** **At Jan-2016, this regulation is revised, but only the following sentence is added;** **The manufacturer must comply with the Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP standards.**	Chemical products: In case major change, approval is needed within 30 days by submission of variation application. For minor change, it should be notified to the authorities within 30 days. (See Drugs and Cosmetics Rules, 1945) Biological products: LEVEL I - Supplements (Major Quality Changes); LEVEL II - Notifiable Changes (Moderate Quality Changes) LEVEL III - Annual Notification (Minor Quality Changes) (See Guidance for Industry: Post approval changes in Biologic Products – Quality, Safety and Efficacy Documents)	**Regulation of the Head of National Agency of Drug and Food Control No HK.03.1.23.10.11.08481 : Criteria and Procedure of Drug Registration, 12 Oct 2011, variation is defined as a change to any aspect of a marketing authorization, including but not limited to a change to formulation, methods, and site of manufacturer, specifications (both for finished product and ingredients), container, packaging, labeling, manufacturing process and product information.**	Partial change application should be submitted for approval of changes. For minor changes, notification system can be applied. Scope and handling of these changes are stipulated in the Pharmaceutical Affairs Law and several notices.	Changes in post-license should be applyed to MFDS according to the level of the changes. Pharmaceutical Affairs Act, Several notices and Guidelines exist.	Malaysian Variation Guideline For Pharmaceutical Products **This guidance document is adopted from the ASEAN Variation Guideline for Pharmaceutical Products 2012 incorporating Malaysia's specific requirements.**	**FDA Circular No. 2014-008: Application Process and Requirements for Post-approval Changes of Pharmaceutical Products, 28 Feb 2014, which was effective on 1 April 2014.** **Almost the same with "Asean variation guideline" , but a country specific request was added.**	There are two sub-categories for each Major and Minor variation. Related Guideline: Guidelines are found in Chapter G in "Guidance on Medicinal Product Registration in Singapore" for MAV, and in chapter H, Appendix 15 and Appendix 16.(each Appendix was updated guideline, effective as of Apr. 1st, 2014). Also partial change of MIV-1/MIV-2 checklists is effective as of Apr. 1st, 2014.	"Drug review and registration guideline" was specify the document needed for post approval change.	Yes, "ASEAN variation guideline" which will be implemented in Jul 2013. ASEAN Variation Guideline

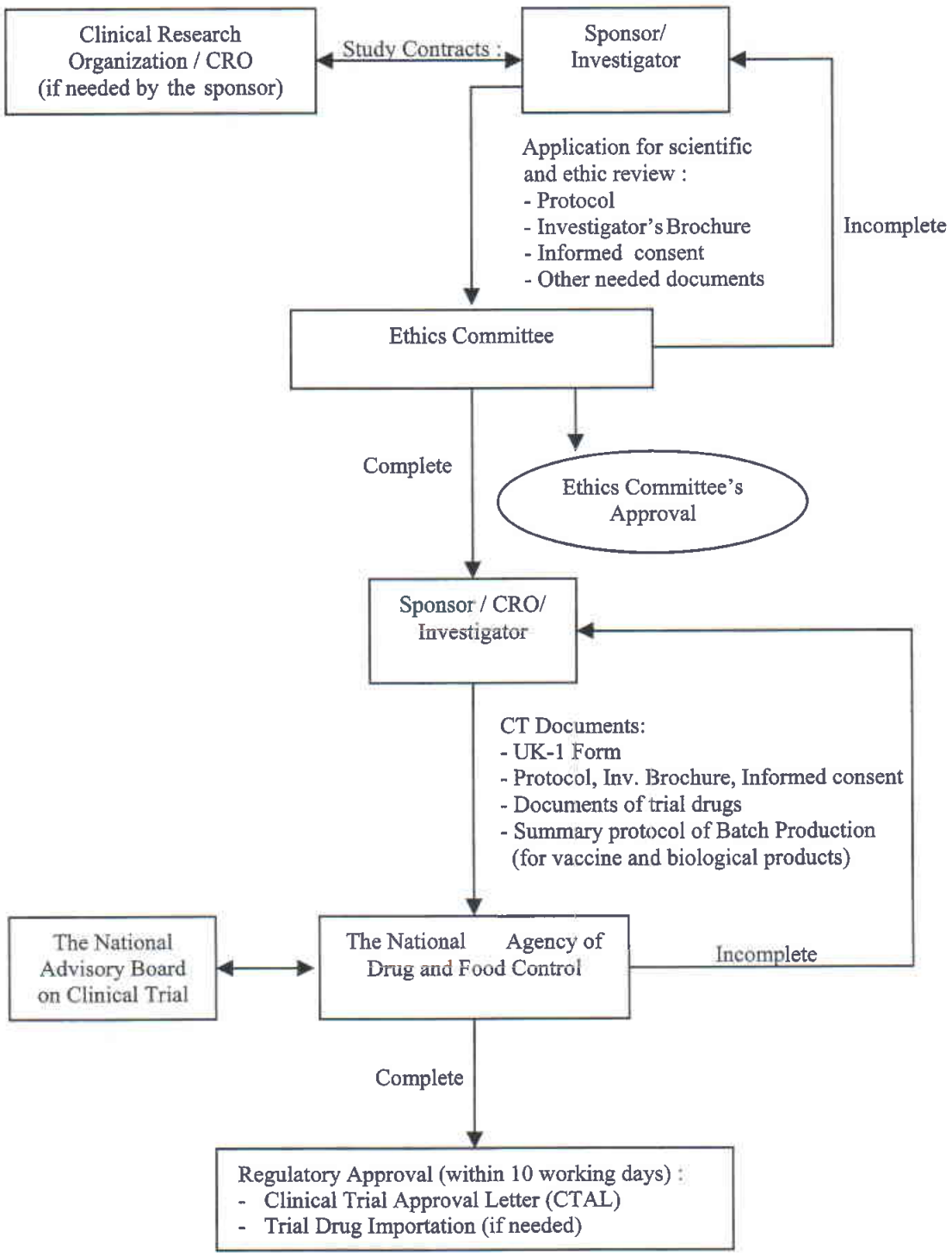
ATTACHMENT IIa
DECREE OF THE HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA
NO 02002/SK/KBPOM
REGARDING CLINICAL TRIAL PROCEDURE

Flow Chart
Pre-Marketing Trial



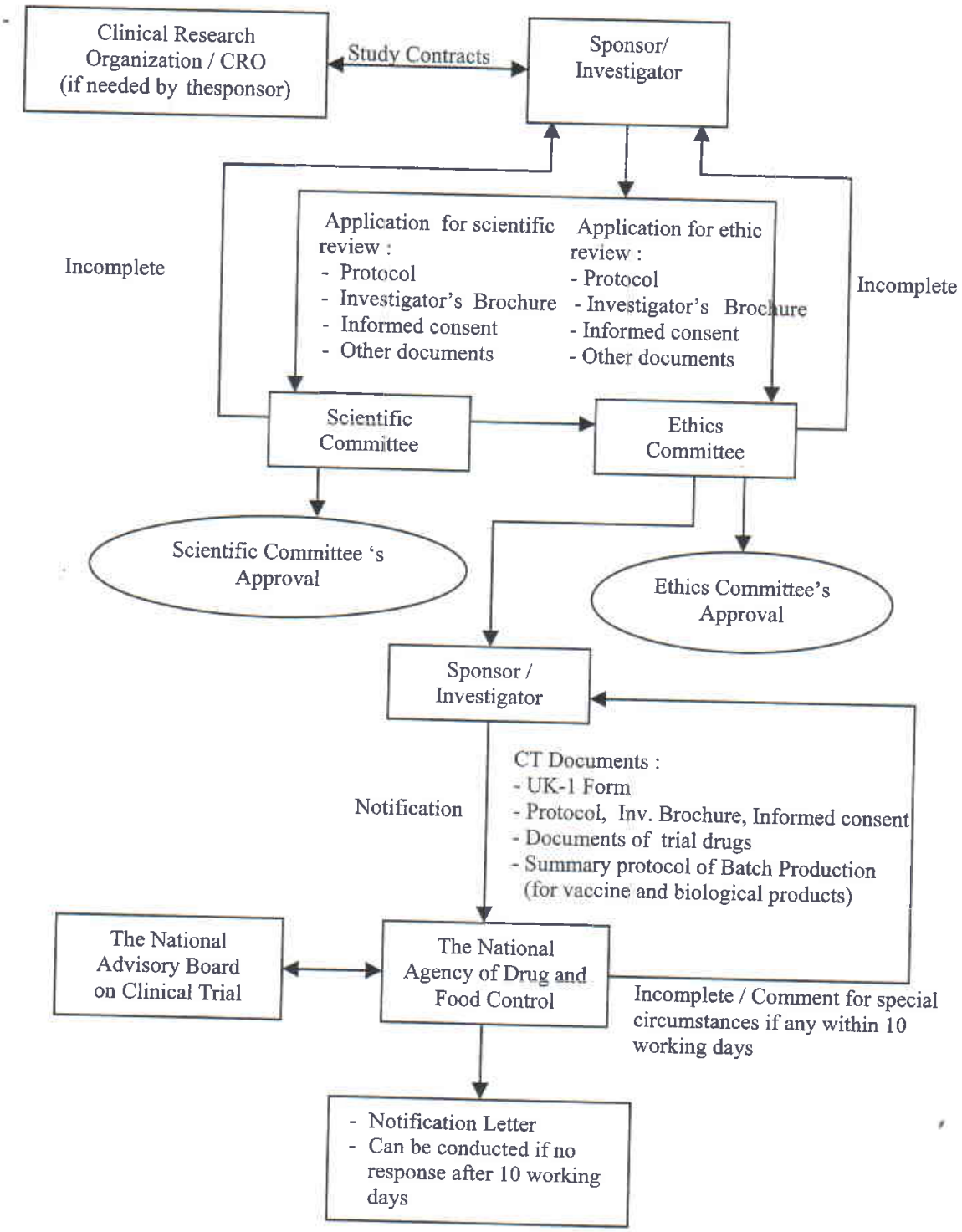
ATTACHMENT IIb
DECREE OF THE HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA
NO 02002/SK/KBPOM
REGARDING CLINICAL TRIAL PROCEDURE

Flow Chart
Pre-Marketing Trial
(Inseparate Scientific and Ethics Committee)



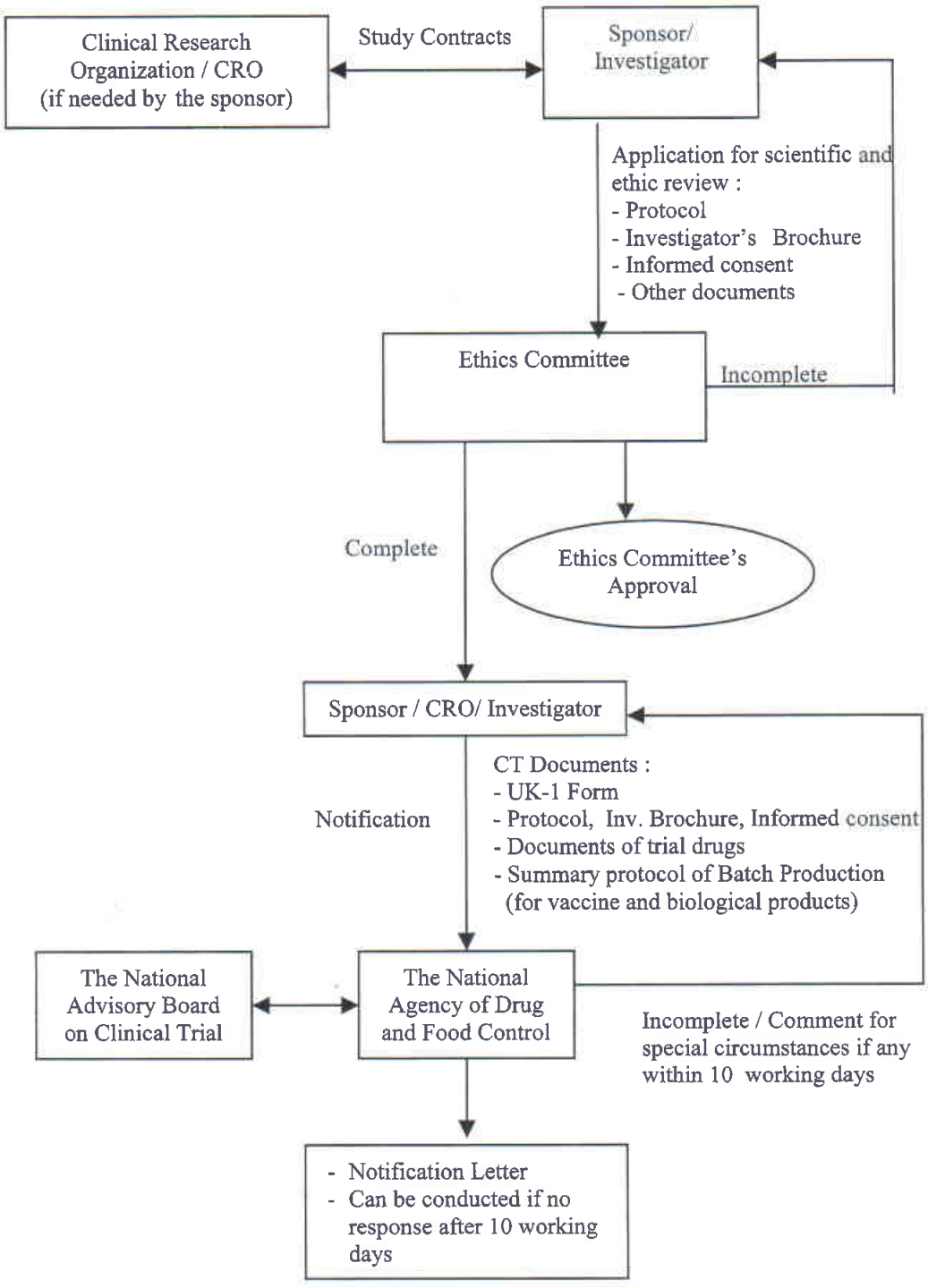
ATTACHMENT IIIa
DECREE OF THE HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA
NO 02002/SK/KBPOM
REGARDING CLINICAL TRIAL PROCEDURE

Flow Chart
Post-Marketing Trial
(Separate Scientific and Ethics Committee)



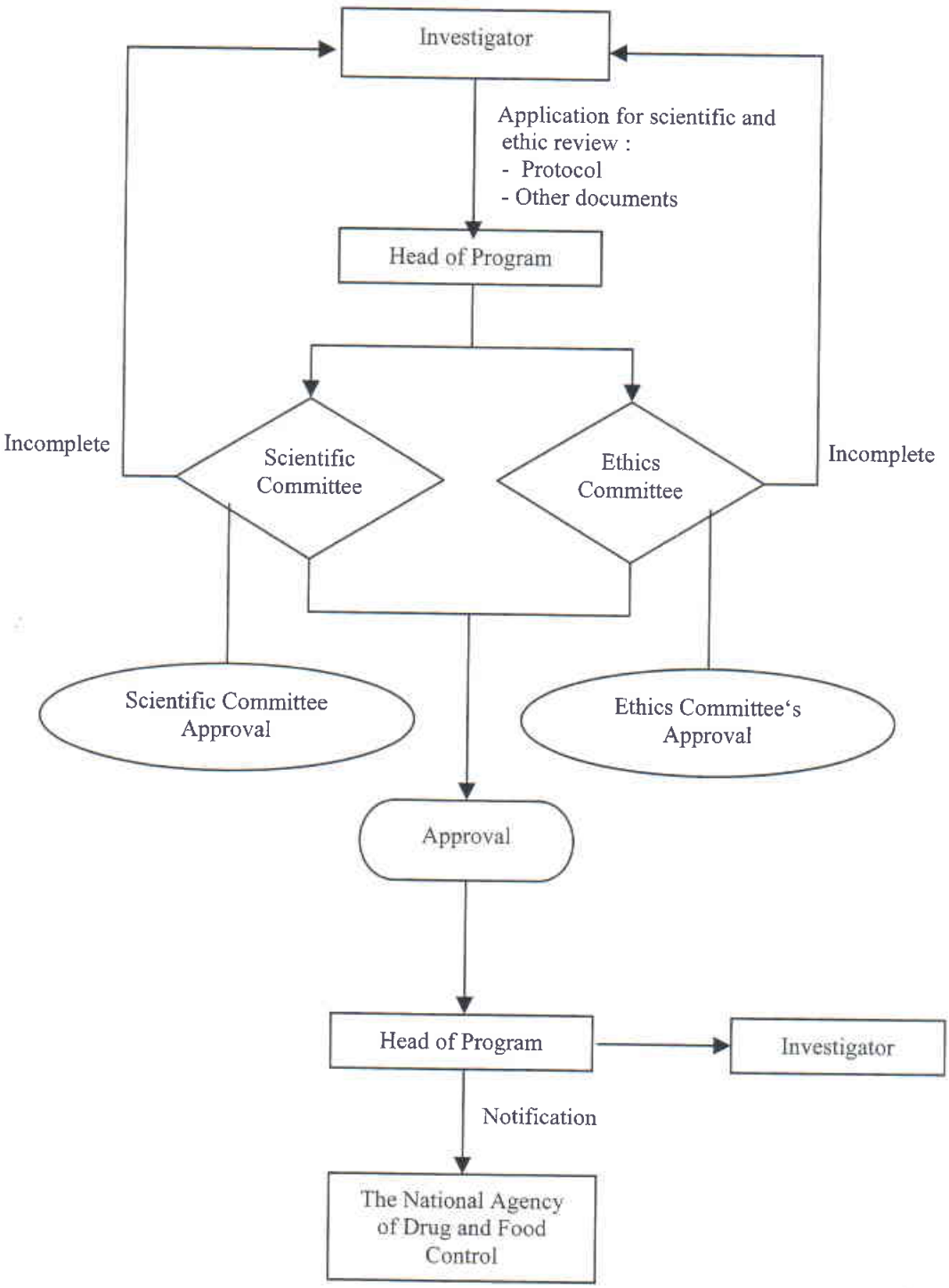
ATTACHMENT IIIb
DECREE OF THE HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA
NO 02002/SK/KBPOM
REGARDING CLINICAL TRIAL PROCEDURE

Flow Chart
Post-Marketing Trial
(Inseparate Scientific and Ethics Committee)



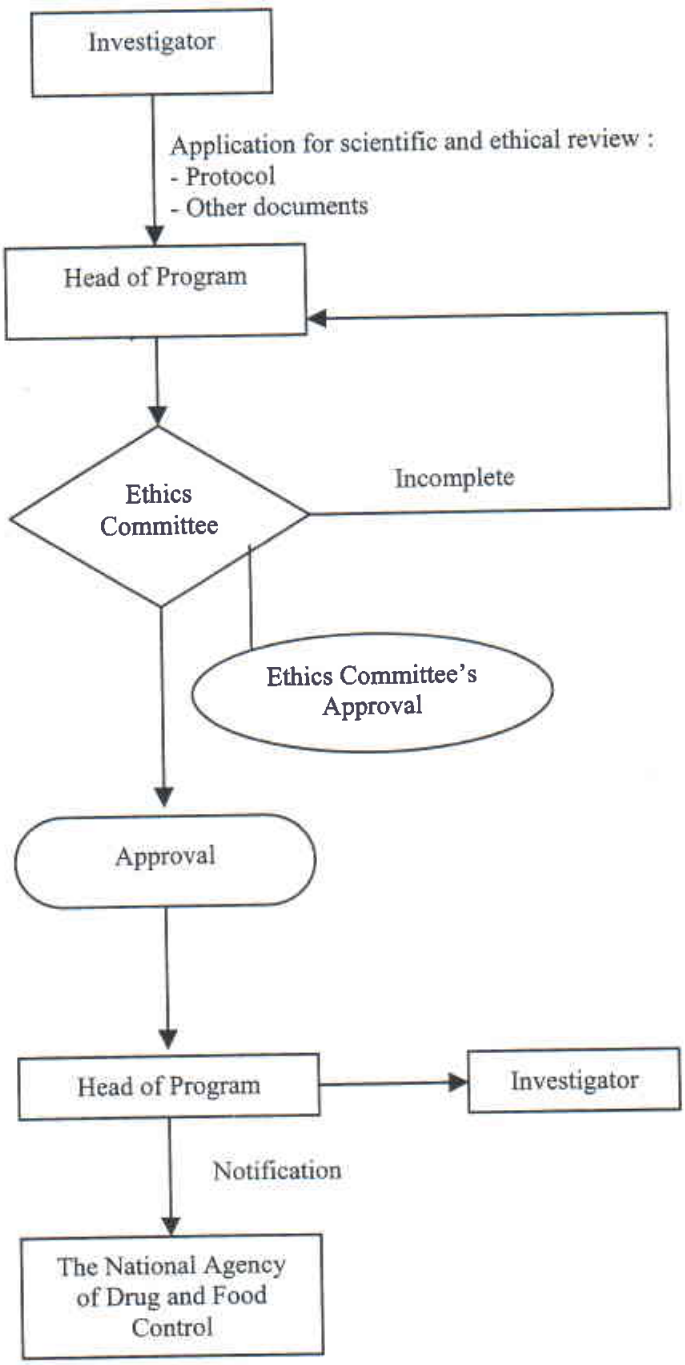
ATTACHMENT IVa
DECREE OF THE HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA
NO 02002/SK/KBPOM
REGARDING CLINICAL TRIAL PROCEDURE

Flow Chart
Trial for Educational Purpose
(Separate Scientific and Ethics Committee)



ATTACHMENT IVb
DECREE OF THE HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA
NO 02002/SK/KBPOM
REGARDING CLINICAL TRIAL PROCEDURE

Flow Chart
Trial for Educational Purposes
(Inseparate Scientific and Ethics Committee)



UK-1 FORM

ATTACHMENT I
DECRRE OF THE HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA
NO 02002/SK/KBPOM
REGARDING CLINICAL TRIAL PROCEDURES

To:
The Head of the National Agency of Drug and Food Control Republic of Indonesia
Percetakan Negara 23
JAKARTA

☐ Pre-Marketing Clinical Trial ☐ Post-Marketing Clinical Trial

I. GENERAL INFORMATION

1. Title of Clinical Trial:
2. Protocol number and dated (final protocol) :
3. Objective of the trial :
4. Phase of the trial (I, II, III, IV) :
5. Design :
6. Use of comparator drug (s) Yes ☐ No ☐
7. Use of placebo Yes ☐ No ☐
8. Number of Subject :

9. Protocol, Investigator's Brochure, Informed Consent and amandements (if any)

Yes ☐ No ☐

10. The categories of study medications used in the clinical trial

☐ Category I
New study medication that has never been studied in human before.

☐ Category II
New study medication that phase I, II, or III trials is still being conducted.

☐ Category III
Study medication has been marketed and this trial is to be conducted for new indication, new administered, and/or new strength.

☐ Category IV
Study medication has been marketed and its trial is being conducted as Post-Marketing Trial.

II. INSTITUTIONS

Multi-center Clinical Trial

Yes ☐ No ☐

Local Center :

Overseas Center :

Name of the (Principle) Investigators, Sub/Co Investigators, and their institution respectively and coordinating investigator (if any) :

III. STUDY DRUG

Study medication : Imported ☐

Local ☐

1. Generic name :
2. Trade name :
3. Chemical name :
4. Pharmacological Class :
5. Dosage form and strength :
6. Packaging :
7. Route of Administration:
8. Expiry date :
9. Batch number :
10. Certificate of analysis :
11. GMP certificate :
12. Imported drug (s) (Name and amount):
13. Manufacturer (Name and address):
14. Imported by :
15. Marketed in other countries (if any):

IV. COMPARATOR DRUG

Study medication	: Imported	☐
	Local	☐

1. Generic name :
2. Trade name :
3. Chemical name :
4. Pharmacological Class :
5. Dosage form and strength :
6. Packaging :
7. Route of Administration:
8. Expiry date :
9. Batch number :
10. Certificate of analysis :
11. GMP certificate :
12. Imported drugs (Name and amount):
13. Manufacturer (Name and address):
14. Imported by :
15. Marketed in other countries (if any):

V. SPONSOR

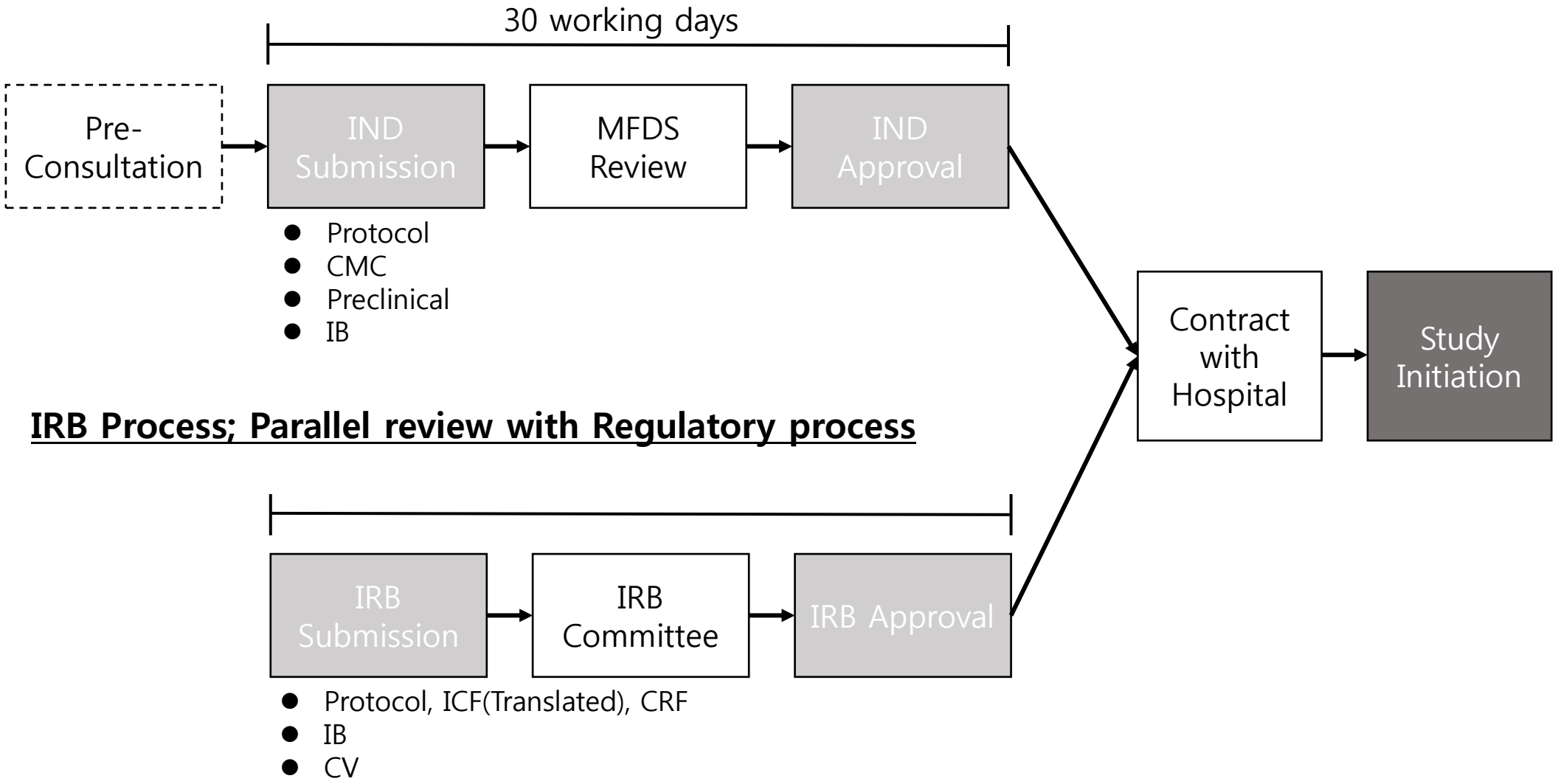
1. Name and address :
2. Sponsor's representative (name and telephone) :
3. Contract Research Organization, (if any, Name and address):

VI. SCIENTIFIC COMMITTEE AND ETHIC COMMITTEE' S APPROVAL

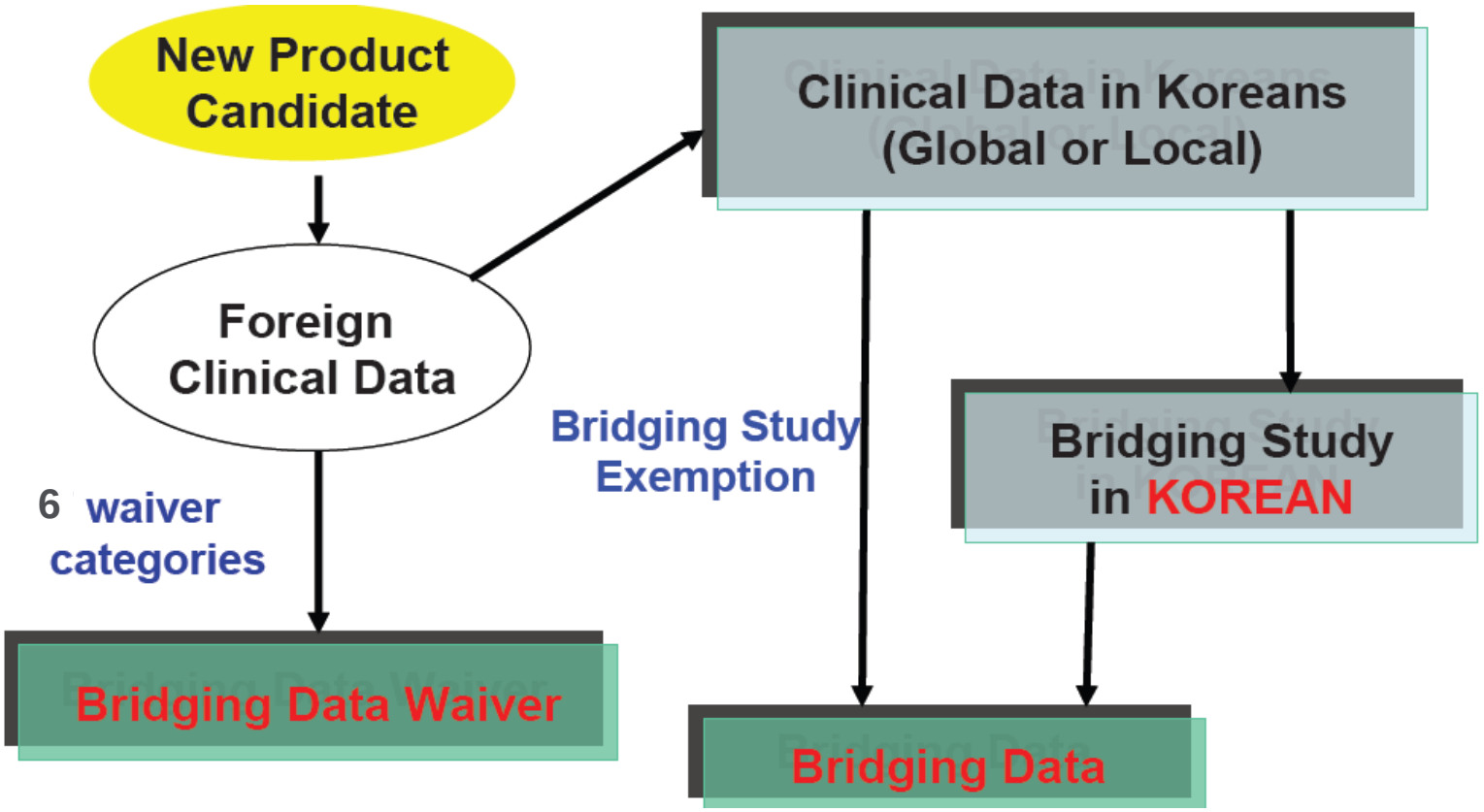
Conclusion of scientific review (attached)
Conclusion of ethical review (attached)
Scientific Committee's approval (attached) - Number and date : - Name and address of Institution :
Ethics Committee' s approval (attached) - Number and date : - Name and address of Institution :

Annex 2

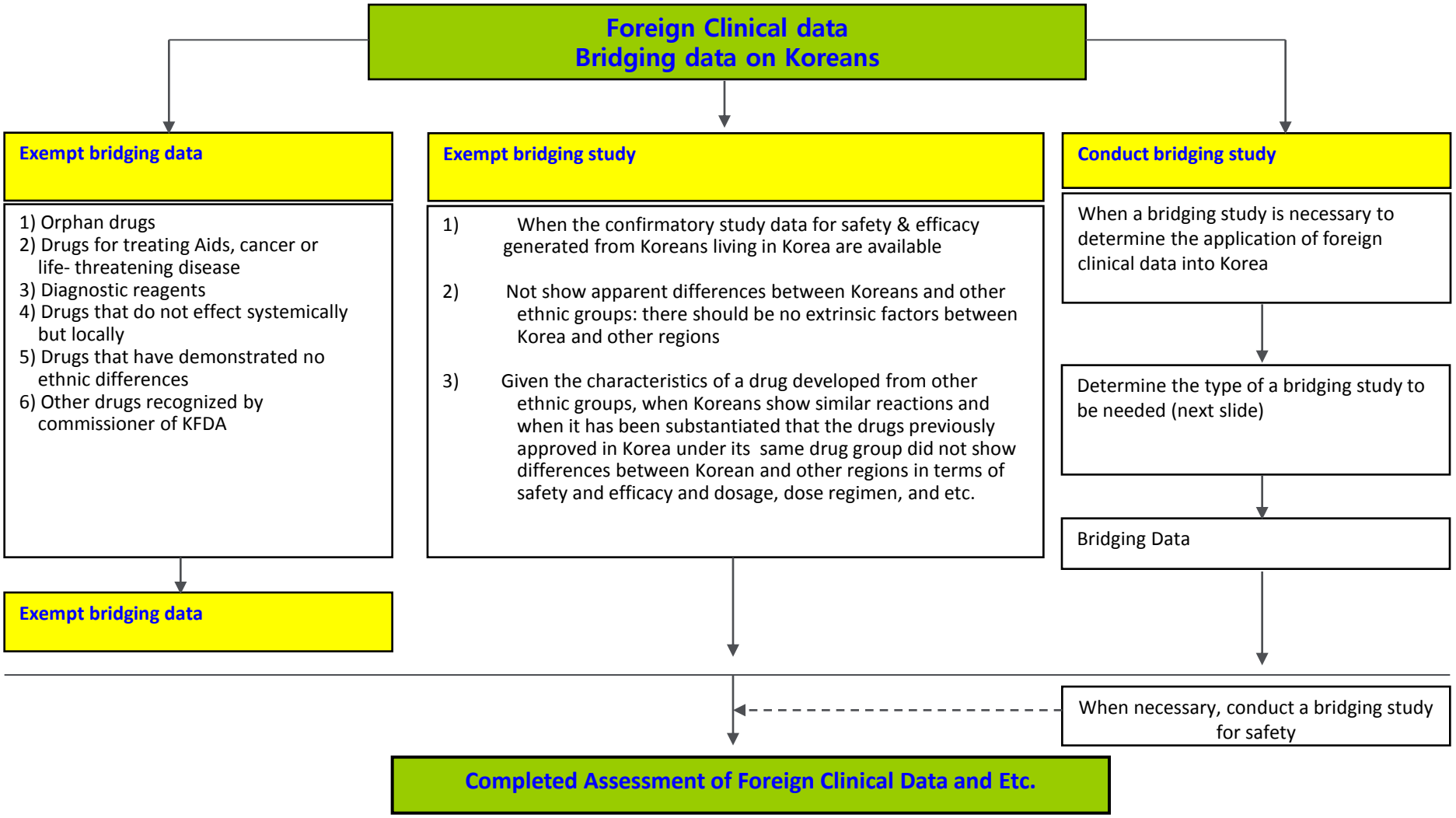
MFDS IND Approval Process



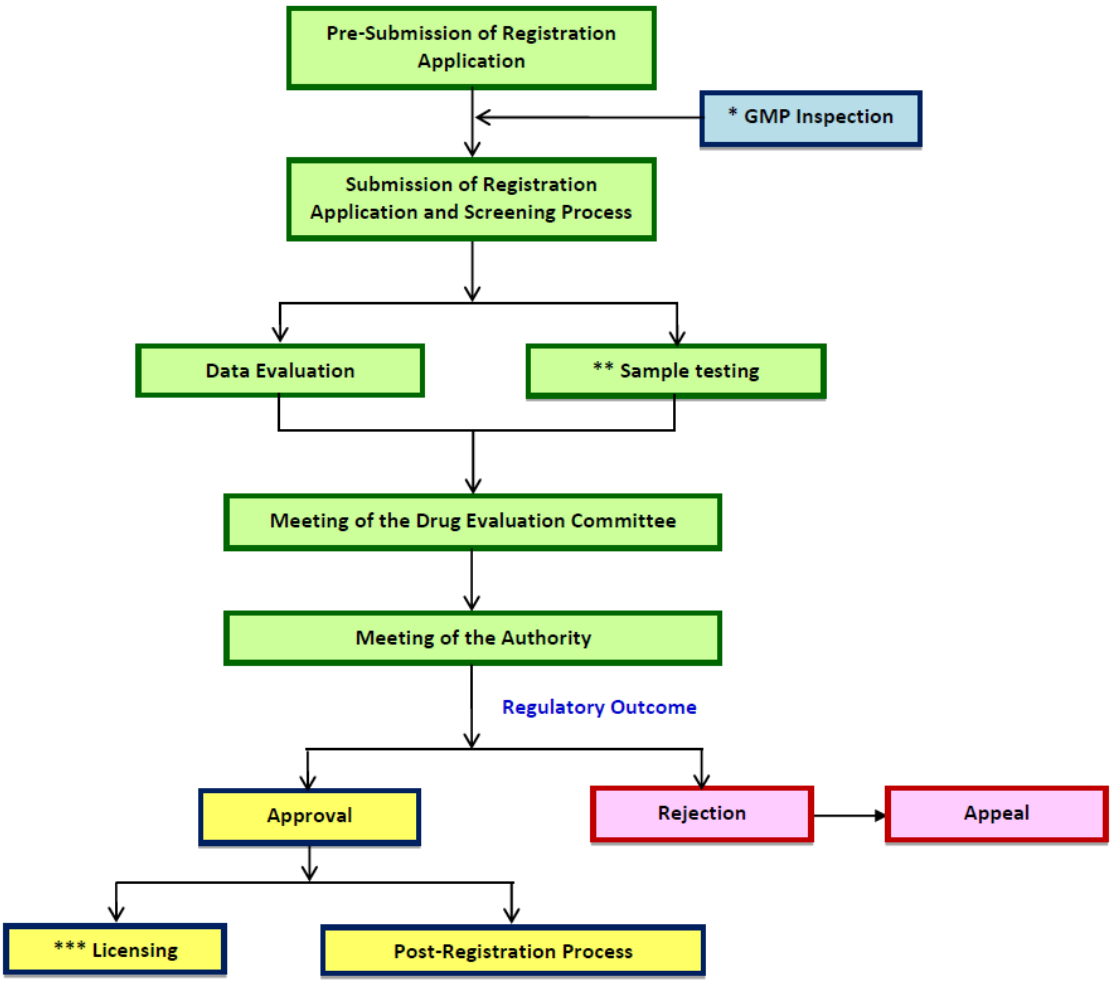
Annex 3


New Product Candidate
Foreign Clinical Data
6 waiver categories
Bridging Data Waiver
Clinical Data in Koreans (Global or Local)
Bridging Study Exemption
Bridging Study in KOREAN
Bridging Data

Annex 3


Foreign Clinical data
Bridging data on Koreans
Exempt bridging data
1) Orphan drugs
2) Drugs for treating Aids, cancer or life- threatening disease
3) Diagnostic reagents
4) Drugs that do not effect systemically but locally
5) Drugs that have demonstrated no ethnic differences
6) Other drugs recognized by commissioner of KFDA
Exempt bridging data
Exempt bridging study
1) When the confirmatory study data for safety & efficacy generated from Koreans living in Korea are available
2) Not show apparent differences between Koreans and other ethnic groups: there should be no extrinsic factors between Korea and other regions
3) Given the characteristics of a drug developed from other ethnic groups, when Koreans show similar reactions and when it has been substantiated that the drugs previously approved in Korea under its same drug group did not show differences between Korean and other regions in terms of safety and efficacy and dosage, dose regimen, and etc.
Conduct bridging study
When a bridging study is necessary to determine the application of foreign clinical data into Korea
Determine the type of a bridging study to be needed (next slide)
Bridging Data
When necessary, conduct a bridging study for safety
Completed Assessment of Foreign Clinical Data and Etc.

Registration process includes quality control, inspection & licensing as well as post-registration process of medicinal products is illustrated in **Figure 2** below:



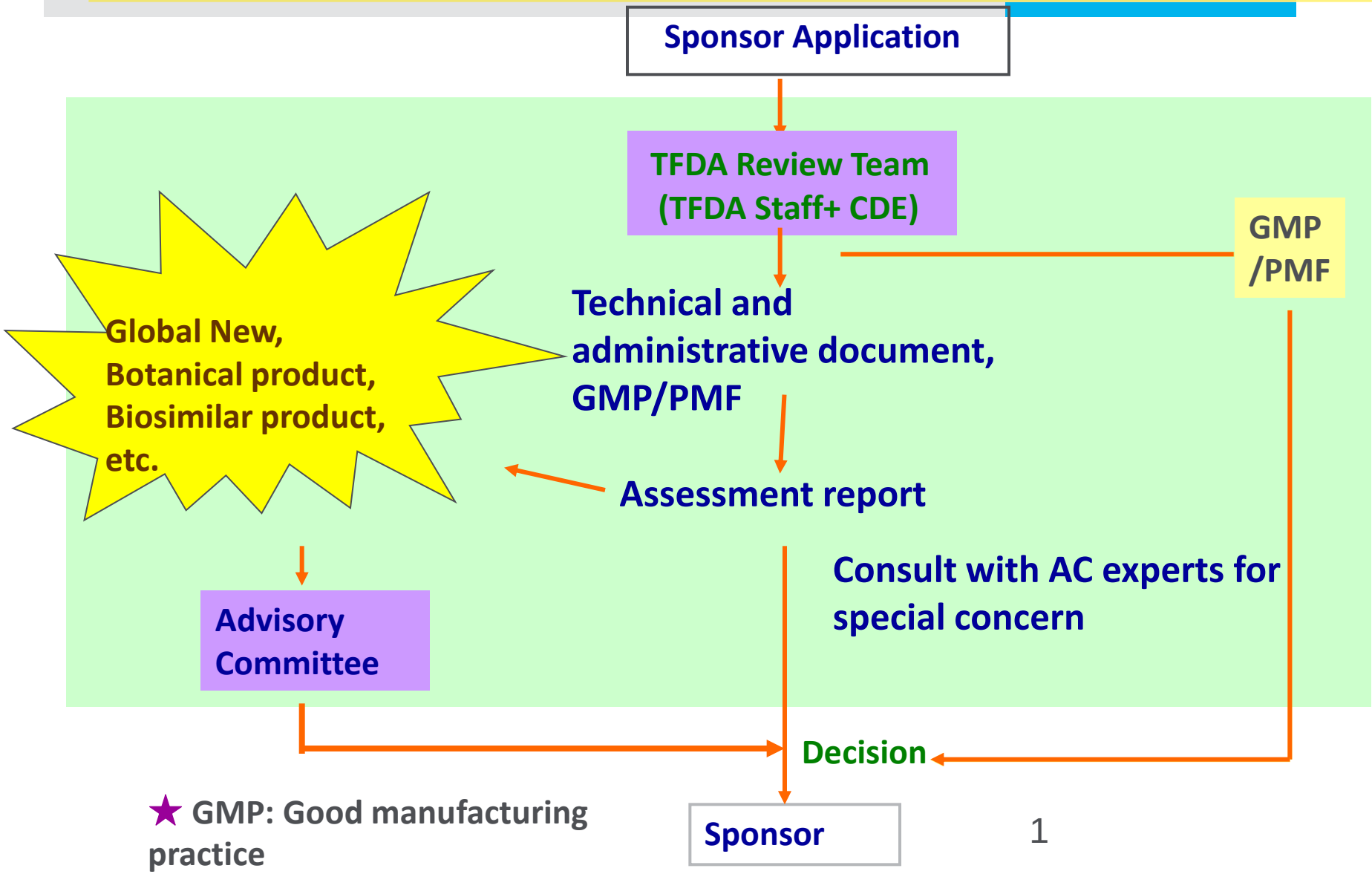
* Good Manufacturing Practice (GMP) Certification

** For natural products only

*** Application for Manufacturer, Import and/or Wholesale License

Review Process for NDA

Annex 5

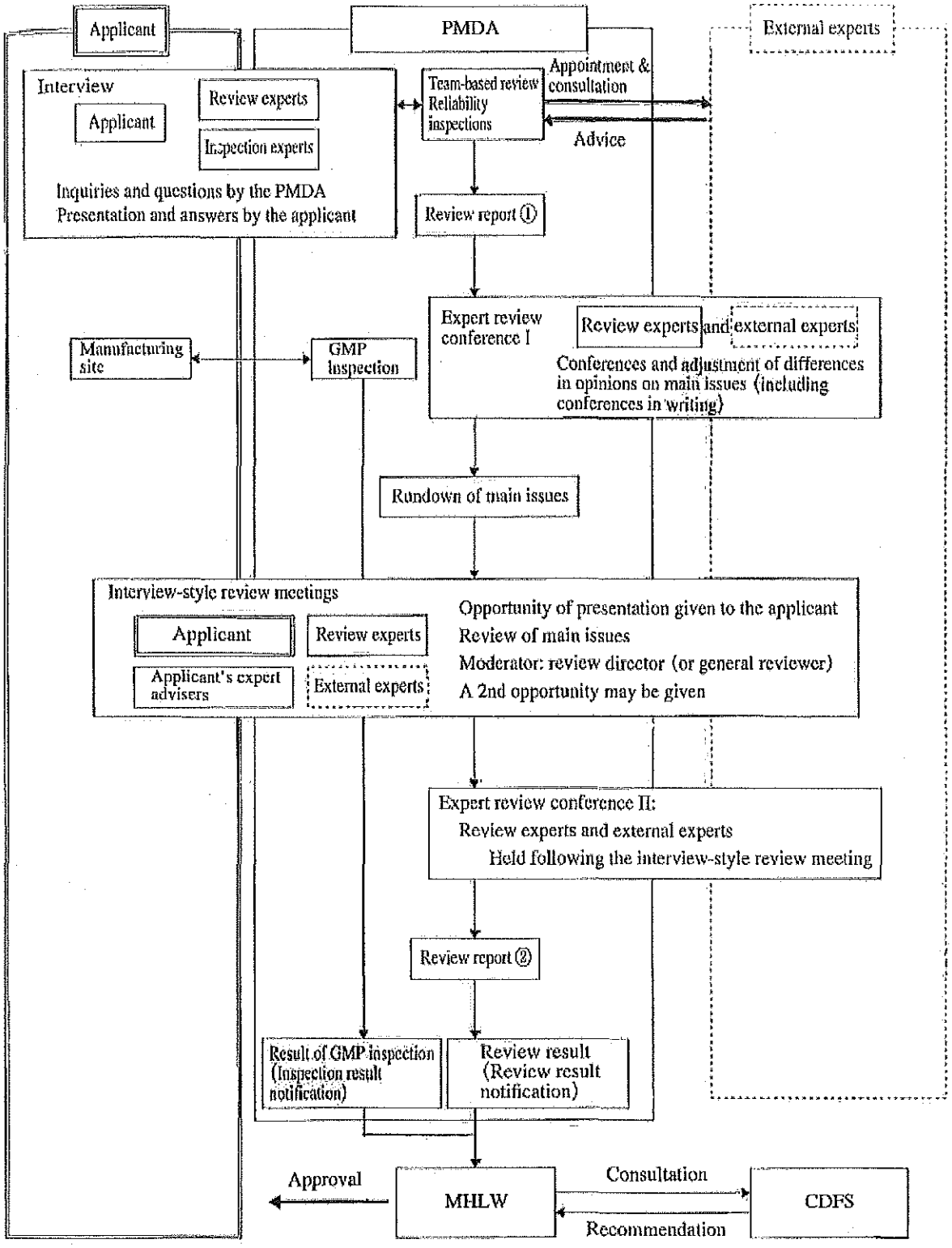


★ GMP: Good manufacturing practice

PMF: Plant master file

1

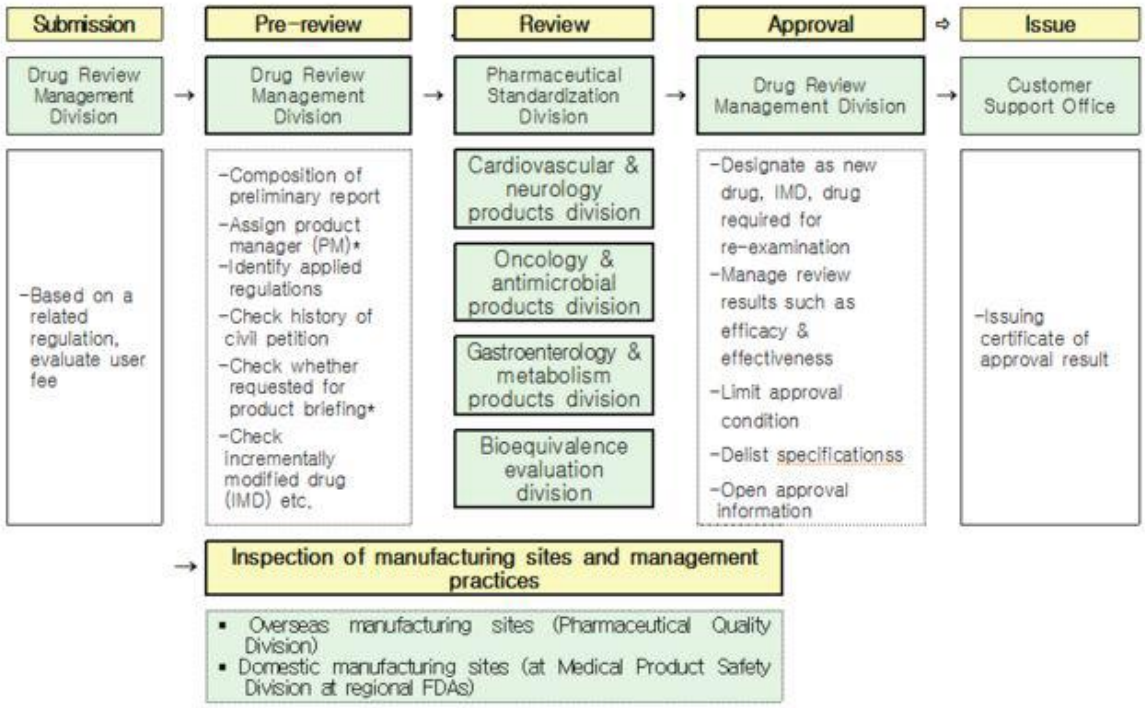
Application Review Process



(Source: Jiho. Drug Approval Licensing Procedures in Japan 2010. Tokyo. Jiho, Inc, 2011; P. 489.)

Annex 7

❍ New drug, Pharmaceutical required for data submission



* In the whole process of drug review and approval, consult with Central Pharmaceutical Affairs Advisory Committee (CPAC), if necessary.
* Product Manager (PM) a general manager from submission, pre-review, supplementation, approval and revision for each product
* Pre-review system : PM examines submission data and the adequacy of data requirements
* Product Briefing
.(Priority) new drug, IMD and when requested by civil petitioner
.(Participants) civil petitioner, Review Division, Pharmaceutical Policy Division
.Improve efficiency and predictability of review and approval process by enhancing mutual understanding between reviewer and petitioner of a product required for approval process
* Drug Approval Update
.Weekly withdrawals, monthly approvals, approval report (NDA), evaluation results of safety and efficacy (pharmaceuticals required for data submission)

❍ Generic Drug
- Required Application Documents : Bioequivalence study, GMP documents and CMC(Chemistry, Manufacturing, Controls) data

Number of reviewers	New Drugs							New Generic (NG)	Generic (G)	Biologics		
	NCE	NI	NCO	ND	NR	NDOS	NS			NB	BF	B
CMC	2	-	2	2	2	2	2	2	2	2	2	2
Clinical	2	2	2	2	2	2	2	2(BA/BE)	-	2	1	
Non-clinical	2	2*	1*	1*	1*	-	1*	(labelling,efficacy&safety	(labelling,efficacy&safety	2	1	1(labelling,efficacy&safety)

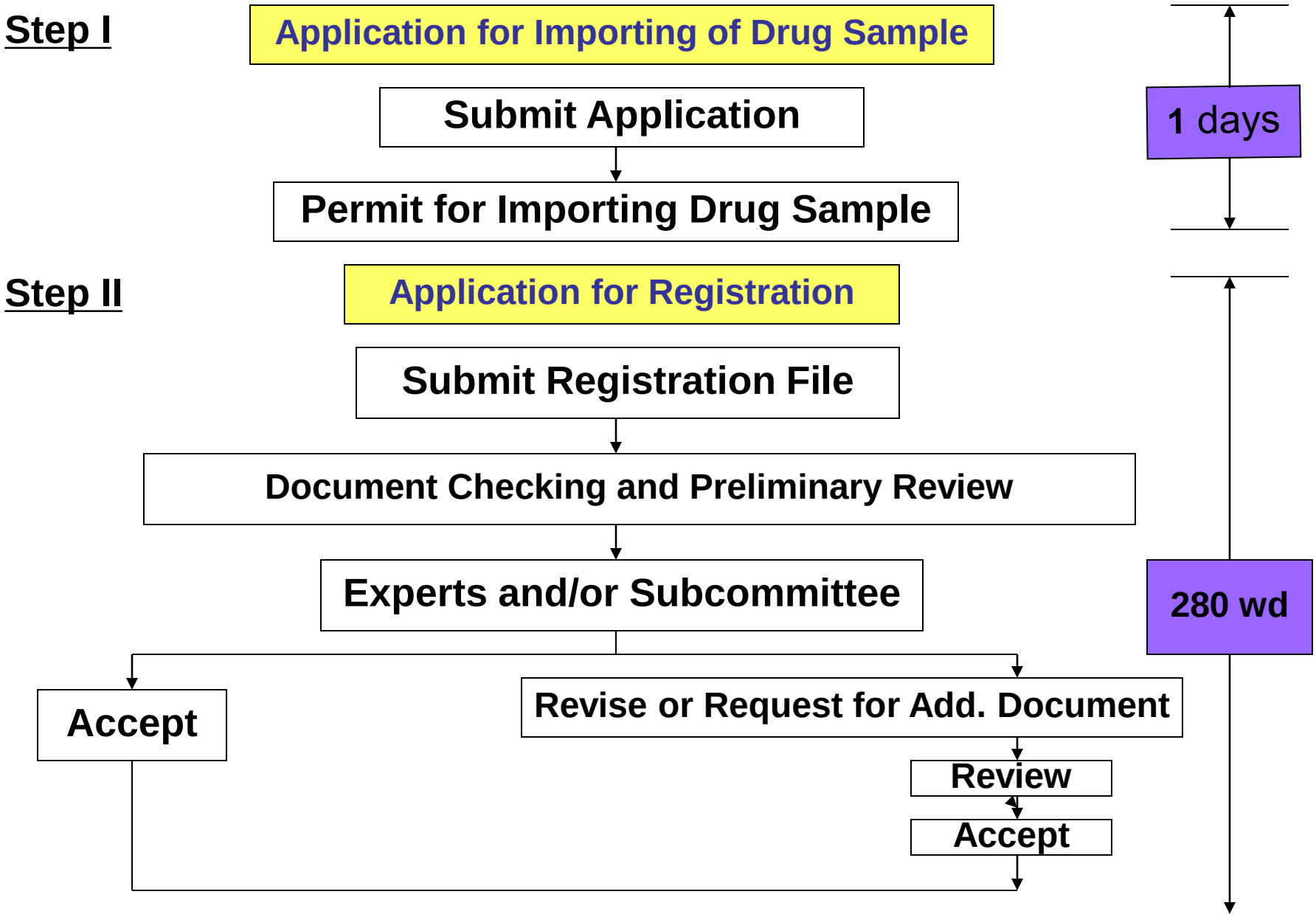
* If applicable

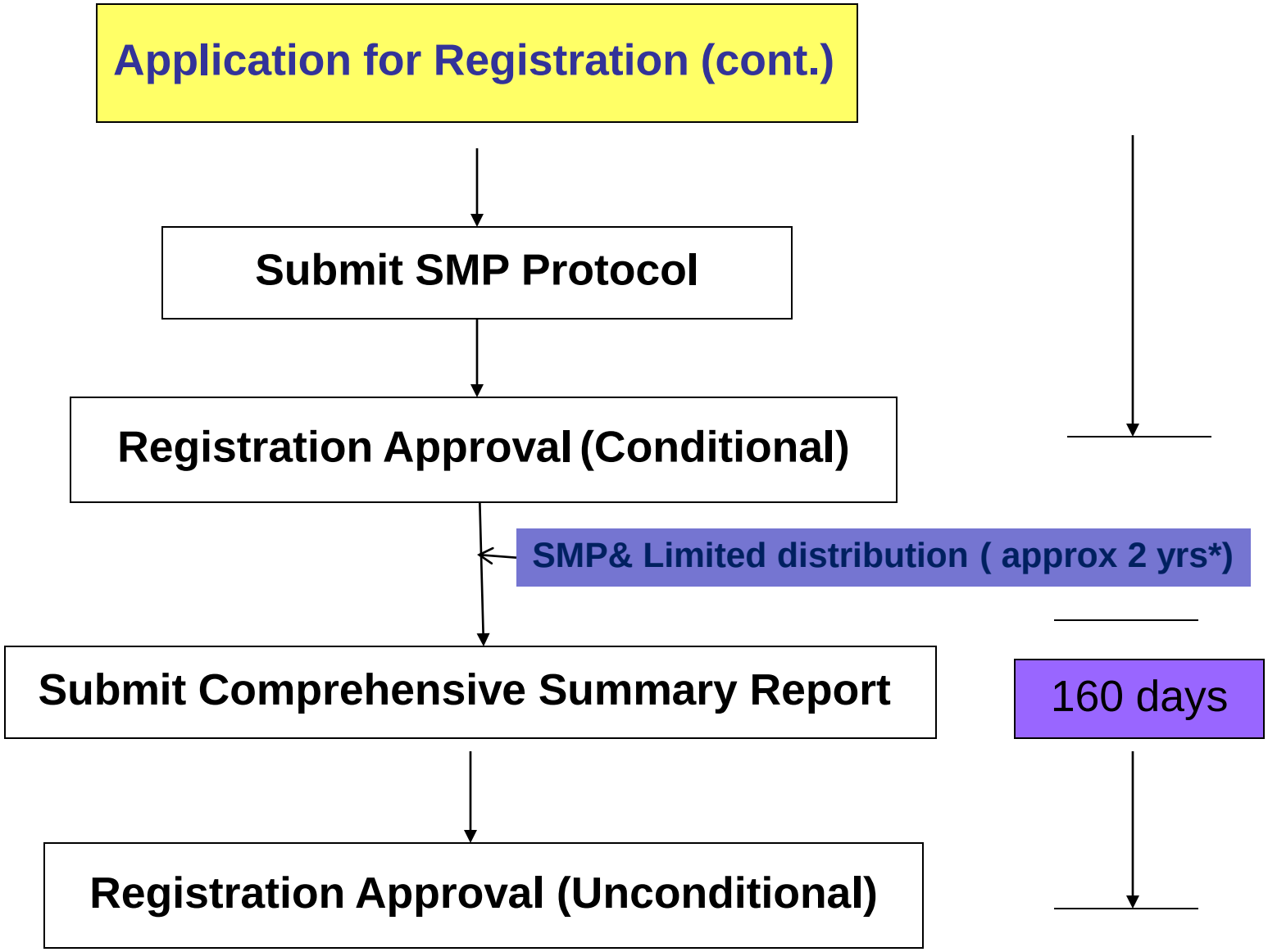
NCE = New Chemical Entity,
NI = New Indication,
NCO = New Combination,
ND = New Delivery system,
NR = New Route of administration,
NDOS = New Dosage form of Approved New Drug,
NS = New Strength of Approved New Drug
NB = New Biological drug
BF = New Generic of Biological drug

New Drug Registration
Thailand

REGISTRATION PROCEDURE

FDA Drug Bureau





Note: *Time can be extended from 2 years up to 4 years if justified

Annex 10

[emblem]

The Announcement of Food and Drug Administration

Title: Guidance for Market Authorization Holders on Post-Marketing Safety Reporting for Human Drugs, Narcotics, and Medicinal Neuropsychotropic Substances

In order to provide the single direction and standard as well as the definite working procedure of post-marketing adverse events reporting and monitoring related to health products to Market Authorization Holders consequence to their compliance and optimizing the pharmacovigilance effectiveness, therefore Food and Drug Administration of Thailand has been issued the announcement entitled “Guidance for Market Authorization Holders on Post-Marketing Safety Reporting for Human Drugs, Narcotics, and Medicinal Neuropsychotropic Substances” as detail enclosed.

Hence, this will be effective from now on.

The announcement on 18 December 2015

[signature]

(Mr. Boonchai Somboonsook)

General Secretary of Food and Drug Administration

The enclosure of

the Announcement of Food and Drug Administration

Title

Guidance for Market Authorization Holders on

Post-Marketing Safety Reporting for

Human Drugs, Narcotics, and Medicinal Neuropsychotropic Substances

Dated 18 December 2015

Table of Contents

Annex 11

Central Drugs Standards Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
(Office of DCGI)

FDA Bhavan, Kotla Road,
New Delhi-110002.

Dated: 26th March, 2016

NOTICE

The Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India, 2012 are in the process of revision. The proposed revised Guidelines on Similar Biologics 2016 are uploaded for suggestions/ comments of the stakeholders.

All the stakeholders are requested to submit their suggestions or comments to the Office of Drugs Controller General (India) by 30th April, 2016 through e-mail (dci@nic.in) or fax (no.011-23236973) or by post to the address as under:

Central Drugs Standards Control Organization HQ,
Office of DCG (I),
FDA Bhavan,
Kotla Road, New Delhi – 110002

Office of Drugs Controller General (India)